IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF INDIANA
SOUTH BEND DIVISION

MARSHALL COUNTY, Plaintiff, vs. PURDUE PHARMA L.P.; PURDUE PHARMA INC.; THE PURDUE FREDERICK COMPANY, INC.; CEPHALON, INC.; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; TEVA PHARMACEUTICALS USA, INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. N/K/A JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA, INC. N/K/A JANSSEN PHARMACEUTICALS, INC.; NORAMCO, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS INC.; MALLINCKRODT PLC; MALLINCKRODT LLC; ALLERGAN PLC F/K/A ACTAVIS PLS; WATSON PHARMACEUTICALS, INC. N/K/A ACTAVIS, INC.; WATSON LABORATORIES, INC.; ACTAVIS, LLC; ACTAVIS PHARMA, INC. F/K/A/ WATSON PHARMA, INC.; AMERISOURCEBERGEN DRUG CORPORATION; CARDINAL HEALTH, INC.; and MCKESSON CORPORATION, Defendants.	)	No. 3:18-cv-46 JURY TRIAL DEMANDED

COMPLAINT

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INTRODUCTION

Plaintiff Marshall County, by counsel, for its Complaint against Defendants Purdue Pharma L.P., Purdue Pharma Inc., The Purdue Frederick Company, Inc., Cephalon, Inc., Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., Johnson & Johnson, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals Inc., Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, Inc., Noramco, Inc., Endo Health Solutions Inc., Endo Pharmaceuticals Inc., Mallinckrodt Plc, Mallinckrodt LLC, Allergan PLC f/k/a Actavis PLS, Watson Pharmaceuticals, Inc. n/k/a Actavis, Inc., Watson Laboratories, Inc., Actavis, LLC, Actavis Pharma, Inc. f/k/a/ Watson Pharma, Inc., ("Manufacturer Defendants"), AmerisourceBergen Drug Corporation; Cardinal Health, Inc., and McKesson Corporation ("Distributor Defendants") (collectively "Defendants") allege as follows:

NATURE OF THIS ACTION

1. Opioid addiction is ravaging Marshall County:

- In Marshall County, the opioid prescription rate per 100 residents for 2012 was 100 and the rate peaked at 102 in 2013.
- According to Marshall County Health Department figures, the number of overdose deaths due to opioid and prescription drug abuse went from one in 2015 to 13 in 2016 and 16 in 2017.

2. A dramatic increase in the use of prescription opioid pain medications, brought on by Manufacturer Defendants' deceptive marketing campaign and Defendants' failure to identify, report, and stop suspicious orders of those medications, has caused this growing crisis.

3. Plaintiff brings this action to eliminate the hazard to public health and safety caused by the opioid epidemic, to abate the nuisance caused thereby, and to recoup monies spent because of Defendants' actions. These economic damages were foreseeable to Defendants and were caused by Defendants' actions.

4. Plaintiff spends substantial sums of money each year to provide or pay for necessary services and programs on behalf of Marshall County residents affected by the opioid epidemic. Plaintiff also provides a wide range of other services on behalf of its residents, including services for families and children, public assistance, and law enforcement, the costs of which have all dramatically increased because of Defendants' misconduct.

5. Opioids include brand-name drugs like OxyContin and generics like oxycodone and hydrocodone. They are derived from or possess properties similar to opium and heroin, are highly addictive and dangerous, and are regulated by the United States Food and Drug Administration ("FDA") and under the Controlled Substances Act ("CSA") as Schedule II controlled substances. Substances in this schedule have a high potential for abuse, which may lead to severe psychological or physical dependence, and are dangerous.

6. Opioids provide effective treatment for short-term post-surgical and trauma-related pain, and for palliative end-of-life care. Manufacturer Defendants, however, have manufactured, promoted, and marketed opioids for the management of other forms of pain by misleading consumers and medical providers through misrepresentations or omissions regarding the appropriate uses, risks, and safety of opioids.

7. Addiction is a spectrum of substance use disorders ("SUDs") that range from misuse and abuse of drugs to addiction.[1] Manufacturer Defendants knew that, barring exceptional circumstances, opioids are too addictive and too debilitating for long-term use for chronic non-cancer pain lasting three months or longer ("chronic pain").

[1] Diagnostic and Statistical Manual of Mental Disorders (5th ed. 2013) ("DSM-V").

8. Manufacturer Defendants knew that, with prolonged use, the effectiveness of opioids wanes, requiring increases in doses to achieve pain relief and increasing the risk of significant side effects and addiction.[2]

9. Manufacturer Defendants knew that controlled studies of the safety and efficacy of opioids were limited to short-term use in managed settings (e.g., hospitals) where the risk of addiction and other adverse outcomes was minimized.

10. To date, there have been no long-term studies demonstrating the safety and efficacy of opioids for long-term use.

11. In 2017, the U.S. Food and Drug Administration requested "that Endo Pharmaceuticals remove its opioid pain medication, reformulated Opana ER (oxymorphone hydrochloride), from the market."[3] The agency sought removal "based on its concern that the benefits of the drug may no longer outweigh its risks."[4]

12. Despite their knowledge, to expand the market for opioids and realize blockbuster profits, Manufacturer Defendants sought to create a false perception of the safety and efficacy of opioids in the minds of medical professionals and members of the public, even going so far as to target veterans, to encourage the use of opioids for longer periods of time and to treat a wider range of problems, including such common aches and pains as lower back pain, arthritis, and headaches.

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[2] *See, e.g.*, Portenoy, Russell K., "Opioid Therapy for Chronic Nonmalignant Pain: Current Status," *1 Progress in Pain Res. & Mgmt.*, 247-287 (H.L. Fields and J.C. Liebeskind eds., 1994).

[3] FDA News Release, "FDA Requests Removal of Opana ER for Risks Related to Abuse, June 8, 2017, *U.S. Food & Drug Administration*, 8 June 2017. Web. 10 Oct. 2017.

[4] *Id.*

13. Manufacturer Defendants successfully created that false perception through a coordinated, sophisticated, and highly deceptive marketing campaign. Manufacturer Defendants accomplished their marketing campaign goal by convincing doctors, patients, and others, including veterans, that the benefits of using opioids to treat chronic pain outweighed the risks, and that opioids could be safely used by most patients. Manufacturer Defendants, individually and collectively, knowing that long-term opioid use causes addiction, misrepresented the dangers of long-term opioid use to physicians, pharmacists, and patients by engaging in a campaign to minimize the risks of, and to encourage, long-term opioid use.

14. Manufacturer Defendants' marketing campaign has succeeded in expanding opioid use. In 2010, 20% of all doctors' visits resulted in the prescription of an opioid (nearly double the rate in 2000).[5] While Americans represent only 4.6% of the world's population, they consume 80% of the opioids supplied around the world and 99% of the global hydrocodone supply.[6] By 2014, nearly two million Americans either abused or were dependent on opioids.[7]

15. Manufacturer Defendants' campaign has been profitable for them. In 2012 alone, opioids generated $8 billion in revenue for drug companies.[8] Of that amount, $3.1 billion

[5] Daubresse, M. et al., "Ambulatory Diagnosis and Treatment of Nonmalignant Pain in the United States," 2000-2010, 51(10) Med. Care 870-78 (2013).

[6] Manchikanti, L. et al., "Therapeutic Use, Abuse, and Nonmedical Use of Opioids: A Ten-Year Perspective," 13 Pain Physician 401-435 (2010).

[7] "CDC Guideline for Prescribing Opioids for Chronic Pain," *Centers for Disease Control and Prevention*. Web. 24 Oct. 2017.

[8] *See* "The Soaring Cost of the Opioid Economy," *The New York Times*, 22 June 2013. Web. 10 Oct. 2017.

went to Purdue for its OxyContin sales. [9] Purdue Pharma is 100% owned by the Sackler family, the 16th richest family in America with a $14 billion net worth, who made their fortune on OxyContin. [10]

16. Manufacturer Defendants' marketing campaign has achieved no material health care benefits. Since 1999, there has been no overall change in pain that Americans report. [11]

17. The National Institutes of Health ("NIH") not only recognizes the opioid abuse problem, but also identifies Manufacturer Defendants' "aggressive marketing" as a major cause: "Several factors are likely to have contributed to the severity of the current prescription drug abuse problem. They include drastic increases in the number of prescriptions written and dispensed, greater social acceptability for using medications for different purposes, and *aggressive marketing by pharmaceutical companies*." [12] The drastic increases in the number of prescriptions written and dispensed and the greater social acceptability for using medications for different purposes result directly from the aggressive marketing by pharmaceutical companies.

18. To regulate highly addictive drugs, like opioids, in 1970, Congress devised a "closed" chain of distribution specifically designed to prevent the diversion of legally produced controlled substances into the illicit market.[13] This closed system imposes duties on the

[9] Eban, Katherin, "OxyContin: Purdue Pharma's Painful Medicine, *Fortune.com*, 9 Nov. 2011. Web. 10 Oct. 2017.

[10] Morrell, Alex, "The OxyContin Clan: The $14 Billion Newcomer to Forbes 2015 List of Richest U.S. Families," *Forbes.com*, 1 July 2015. Web. 10 Oct. 2017.

[11] "Prescribing Data," *Centers for Disease Control and Prevention*. Web. 24 Oct. 2017.

[12] Volkow, Nora D., M.D., "America's Addiction to Opioids: Heroin and Prescription Drug Abuse," *National Institute on Drug Abuse*, 14 May 2014. Web. 24 Oct. 2017.

[13] *See Gonzales v. Raich*, 545 U.S. 1, 12–14 (2005); 21 U.S.C. § 801(2); 21 U.S.C. §§ 821-824, 827, 880; H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. 4566, 4572 (Sept. 10, 1970).

Distributor Defendants and Manufacturer Defendants to monitor, identify, halt, and report "suspicious orders" of controlled substances.[14]

19. Distributor Defendants control 85% of the market share for distributing prescription opioids. Distributor Defendants are Fortune 500 corporations on the New York Stock Exchange engaged in the nationwide wholesale distribution of prescription drugs.[15]

20. Data that reveals the specific amount of opioids Distributor Defendants distributed in Indiana and Marshall County is hidden from public view in the DEA's confidential ARCOS database. [16] Neither the DEA[17] nor the Distributor Defendants[18] will voluntarily disclose the data necessary to identify with specificity those transactions.

21. Based on the data publicly available, Distributor Defendants failed to identify, report, and stop obviously suspicious orders, flooding the market with opioid prescriptions in Marshall County. For example, since 1999, the amount of prescription opioids sold in the U.S.

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[14] *See* 21 C.F.R. § 1301.74; *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206 (D.C. Cir. 2017).

[15] *See Fed. Trade Comm'n v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 37 (D.D.C. 1998).

[16] *See Madel v. USDOJ*, 784 F.3d 448 (8th Cir. 2015).

[17] *See* Declaration of Katherine L. Myrick, Chief, Freedom of Information (FOI)/Privacy Act Unit ("SARF"), FOI, Records Management Section ("SAR"), Drug Enforcement Administration (DEA), United States Department of Justice (DOJ) (filed in *Madel v. USDOJ*, Case No. 0:13-cv-02832-PAM-FLN, Doc. 23, ¶ 40 (D. Minn. Feb. 6, 2014) (noting that "the data is kept confidential by the DEA. . .").)

[18] *See* Declaration of Tina Lantz, Cardinal Health VP of Sales Operation, (filed in *Madel v. USDOJ*, Case No. 0:13-cv-02832-PAM-FLN, Doc. 93, ¶ 6 (D. Minn. Nov. 2, 2016) ("Cardinal Health does not customarily release any of the information identified by the DEA notice letter to the public, nor is the information publicly available. Cardinal Health relies on DEA to protect its confidential business information reported to the Agency.").)

nearly quadrupled.[19] In 2010, 254 million prescriptions for opioids were filled in the U.S.—**enough to medicate every adult in America around the clock for a month.** In 2012, Indiana was among a handful of states whose opioid prescriptions roughly equaled its population.[20]

22. A reporter in West Virginia was able to obtain the confidential ARCOS data that Distributor Defendants refuse to release that revealed that "drug companies shipped nearly 9 million [opioid] pills over two years to one pharmacy in the town of Kermit, W. Va., population 392. All told, the newspaper reported, drug wholesalers distributed 780 million pills of oxycodone and hydrocodone in the state over six years."[21] Those shipments amounted to 433 pain pills for every person in West Virginia. The numbers for Indiana will be similarly staggering.

23. Each Distributor Defendant has been investigated—and some fined—by the DEA for failing to report suspicious orders of opioids to the DEA. As recognized by a DEA supervisor, "The distributors are important. They're like the quarterback. They distribute the ball."[22]

24. Defendants' wrongful conduct has been extremely harmful to Marshall County. Overdoses from prescription pain relievers are a driving factor in a 15-year increase in opioid overdose deaths. "Since 1999, the number of overdose deaths involving opioids (including

[19] "Understanding the Epidemic, Drug Overdose Deaths in the United States Continue to Increase in 2015," *Centers for Disease Control and Prevention*. Web. 24 Oct. 2017.

[20] Lapowsky, Issie, "Indiana, Reeling from Opioid Crisis, Arms Officials with Data," *Wired.com*, 14 Sept. 2017. Web. 10 Oct. 2017.

[21] Ornstein, Charles, "Drug Distributors Penalized for Turning Blind Eye in Opioid Epidemic," *NPR.org*, 27 Jan. 2017. Web. 24 Oct. 2017.

[22] *Id.*

prescription opioids and heroin) quadrupled." [23] From 2000 to 2015, more than half a million people died from drug overdoses and 91 Americans die every day from an opioid overdose.[24] From 2000 to 2015, opioid-involved poisoning deaths erased two and a half months from overall life expectancy at birth in the United States.[25] Every 25 minutes a baby is born suffering from opioid withdrawal.[26]

25. On March 22, 2016, the FDA recognized opioid abuse as a "public health crisis" that has a "profound impact on individuals, families and communities across our country."[27]

26. "Prescription opioids, heroin, and synthetic opioid drugs all work through the same mechanism of action."[28] The National Institute on Drug Abuse states that "[p]rescription opioid pain medicines such as OxyContin® and Vicodin® have effects similar to heroin. Research suggests that misuse of these drugs may open the door to heroin use. Nearly 80 percent

[23] "Understanding the Epidemic, Drug Overdose Deaths in the United States Continue to Increase in 2015," *Centers for Disease Control and Prevention*. Web. 24 Oct. 2017.

[24] *Id.*

[25] "Opioid Epidemic Lowers Overall Life Expectancy in U.S.," *The National Law Review*, 10 Oct. 2017. Web. 24 Oct. 2017.

[26] "Dramatic Increases in Maternal Opioid Use and Neonatal Abstinence Syndrome," *National Institute on Drug Abuse*. Web. 24 Oct. 2017.

[27] FDA News Release, "FDA Announces Enhanced Warnings for Immediate-Release Opioid Pain Medications Related to Risks of Misuse, Abuse, Addiction, Overdose and Death," *U.S. Food and Drug Administration*, 22 Mar. 2016. Web. 10 Oct. 2017.

[28] Compton, Wilson M. M.D., "Research on the Use and Misuse of Fentanyl and Other Synthetic Opioids," *National Institute on Drug Abuse*, 30 June 2017. Web. 24 Oct. 2017.

of Americans using heroin (including those in treatment) reported misusing prescription opioids first."[29]

27. "The emergence of illicitly manufactured synthetic opioids including fentanyl, carfentanil, and their analogues represents an escalation of the ongoing opioid overdose epidemic."[30]

28. The rising numbers of persons addicted to opioids have led to increased health care costs and a dramatic increase in social problems, including drug abuse and diversion and the commission of criminal acts to obtain opioids throughout the United States, including Marshall County. Public health and safety throughout the United States, including Marshall County, has been significantly and negatively affected due to widespread inappropriate use of the drugs manufactured and distributed by Defendants.

29. As a direct and foreseeable consequence of Defendants' wrongful conduct, Plaintiff spends substantial sums of money each year in efforts to combat the opioid epidemic created by Defendants' conduct. Plaintiff has incurred and continues to incur costs related to opioid addiction and abuse, including, but not limited to, health care costs, criminal justice and victimization costs, social costs, lost productivity, and lost revenue.

JURISDICTION AND VENUE

30. This Court has jurisdiction over this action under 28 U.S.C. § 1331 based on the federal claims asserted under the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1961, *et seq.* ("RICO"). This Court has supplemental jurisdiction over Plaintiff's state-law

[29] "What is heroin?" *National Institute on Drug Abuse*, Revised July 2017. Web. 24 Oct. 2017.

[30] Compton, Wilson M. M.D., "Research on the Use and Misuse of Fentanyl and Other Synthetic Opioids," *National Institute on Drug Abuse*, 30 June 2017. Web. 24 Oct. 2017.

claims under 28 U.S.C. § 1367 because those claims are so related to Plaintiff's federal claims that they form part of the same cause or controversy.

31. This Court also has subject-matter jurisdiction over this action under 28 U.S.C. § 1332(a) based on complete diversity of citizenship between Plaintiff and all Defendants. The amount in controversy exceeds $75,000, exclusive of interest and costs.

32. This Court has personal jurisdiction over Defendants because they conduct business in Indiana, purposefully direct or directed their actions toward Indiana, consensually submitted to the jurisdiction of Indiana when obtaining a manufacturer or distributor license, and have the requisite minimum contacts with Indiana necessary to constitutionally permit the Court to exercise jurisdiction.

33. Venue is proper in this District under 28 U.S.C. § 1391 and 18 U.S.C. § 1965 because a substantial part of the events or omissions giving rise to the claim occurred in this District and each Defendant transacted affairs and conducted activity that gives rise to the claim of relief in this District.

PARTIES

34. Plaintiff Marshall County is a county in Indiana.

35. Plaintiff provides a wide range of services on behalf of its residents, including services for families and children, public health, public assistance, law enforcement, and emergency care.

36. Defendant Purdue Pharma L.P. ("PPL") is a limited partnership organized under the laws of Delaware with its principal place of business in Stamford, Connecticut.

37. Defendant Purdue Pharma Inc. ("PPI") is a New York corporation with its principal place of business in Stamford, Connecticut.

38. Defendant The Purdue Frederick Company, Inc. ("PFC") is a New York corporation with its principal place of business in Stamford, Connecticut.

39. PPL, PPI, and PFC (collectively, "Purdue") are engaged in the manufacture, promotion, distribution, and sale of opioids nationally and in Marshall County, including the following:

Drug Name	**Chemical Name**	**Schedule**[31]
OxyContin	Oxycodone hydrochloride extended release	Schedule II
MS Contin	Morphine sulfate extended release	Schedule II
Dilaudid	Hydromorphone hydrochloride	Schedule II
Dilaudid-HP	Hydromorphone hydrochloride	Schedule II
Butrans	Byprenorpine	Schedule III
Hysingla ER	Hydrocodone bitrate	Schedule II
Targiniq ER	Oxycodone hydrochloride and naloxone hydrochloride	Schedule II

40. OxyContin is Purdue's largest-selling opioid. Since 2009, Purdue's national annual sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion, up four-fold from 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (i.e., painkillers).

[31] Since passage of the Controlled Substances Act ("CSA") in 1970, opioids have been regulated as controlled substances. As controlled substances, they are categorized in five schedules, ranked in order of their potential for abuse, with Schedule I being the most dangerous. The CSA imposes a hierarchy of restrictions on prescribing and dispensing drugs based on their medicinal value, likelihood of addiction or abuse, and safety. Opioids generally had been categorized as Schedule II or Schedule III drugs. Schedule II drugs have a high potential for abuse, have a currently accepted medical use, and may lead to severe psychological or physical dependence. Schedule III drugs are deemed to have a lower potential for abuse, but their abuse still may lead to moderate or low physical dependence or high psychological dependence.

41. In 2007, Purdue and three of its executives pled guilty to federal criminal charges for misleading regulators, doctors, and patients about OxyContin's risk of addiction and its potential to be abused.[32]

42. Defendant Cephalon, Inc. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania.

43. Defendant Teva Pharmaceutical Industries, Ltd. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petah Tikva, Israel. In 2011, Teva Ltd. acquired Cephalon, Inc.

44. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business in North Wales, Pennsylvania and is a wholly owned subsidiary of Teva Ltd. in Pennsylvania. Teva USA acquired Cephalon in October 2011.

45. Cephalon, Inc., Teva Ltd., and Teva USA (collectively, "Cephalon") work together to manufacture, promote, distribute and sell both brand name and generic versions of the opioids nationally and in Marshall County, including the following:

Drug Name	**Chemical Name**	**Schedule**
Actiq	Fentanyl citrate	Schedule II
Fentora	Fentanyl citrate	Schedule II

46. Teva USA sold generic opioids, including a generic form of OxyContin from 2005 to 2009 nationally and in Marshall County.

47. Defendant Johnson & Johnson ("J&J") is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

[32] Meier, Barry, "In Guilty Plea, OxyContin Maker to Pay $600 Million," *The New York Times*, 10 May 2017. Web. 24 Oct. 2017.

48. Defendant Janssen Pharmaceuticals, Inc. ("Janssen Pharmaceuticals") is a Pennsylvania corporation with is principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of J&J.

49. Janssen Pharmaceuticals, Inc. was formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc., which was formerly known as Janssen Pharmaceutica, Inc.

50. Defendant Noramco, Inc. ("Noramco") is a Delaware company headquartered in Wilmington, Delaware and was a wholly owned subsidiary of J&J until July 2016.

51. Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc. ("OMP"), now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

52. Janssen Pharmaceutica, Inc. ("Janssen Pharmaceutica"), now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

53. J&J is the only company that owns over 10% of Janssen Pharmaceuticals stock. J&J controls the sale and development of Janssen Pharmaceuticals drugs and Janssen Pharmaceuticals profits inure to J&J's benefit.

54. J&J, Janssen Pharmaceuticals, Noramco, OMP, and Janssen Pharmaceutica (collectively, "Janssen") are or have been engaged in the manufacture, promotion, distribution, and sale of opioids nationally and in Marshall County, including the following:

Drug Name	**Chemical Name**	**Schedule**
Duragesic	Fentanyl	Schedule II
Nucynta[33]	Tapentadol extended release	Schedule II
Nucynta ER	Tapentadol	Schedule II

[33] Depomed, Inc. acquired the rights to Nucynta and Nucynta ER from Janssen in 2015.

55. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014. Prior to 2009, Duragesic accounted for at least $1 billion in annual sales.

56. Defendant Endo Health Solutions Inc. ("EHS") is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

57. Defendant Endo Pharmaceuticals Inc. ("EPI") is a wholly owned subsidiary of EHS and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

58. EHS and EPU (collectively, "Endo") manufacture, promote, distribute and sell opioids nationally and in Marshall County, including the following:

Drug Name	**Chemical Name**	**Schedule**
Opana ER	Oxymorphone hydrochloride extended release	Schedule II
Opana	Oxymorphone hydrochloride	Schedule II
Percodan	Oxymorphone hydrochloride and aspirin	Schedule II
Percocet	Oxymorphone hydrochloride and acetaminophen	Schedule II

59. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana ER yielded revenue of $1.15 billion from 2010 to 2013, and it accounted for 10% of Endo's total revenue in 2012. Opana ER was the opioid at the center of the HIV outbreak in Indiana in 2015.[34] After the outbreak, the FDA requested "that Endo Pharmaceuticals remove its opioid pain medication, reformulated Opana ER (oxymorphone hydrochloride), from the

[34] CNN Wire, "FDA wants Opioid at Center of Scott County HIV Outbreak Pulled off Market," *Fox59.com*, 9 June 2017. Web. 25 Oct. 2017.

market."[35] The agency sought removal "based on its concern that the benefits of the drug may no longer outweigh its risks."[36]

60. Endo also manufactures and sells generic opioids, both directly and through its subsidiary, Qualitest Pharmaceuticals, Inc., including generic oxycodone, oxymorphone, hydromorphone, and hydrocodone products.

61. Defendant Mallinckrodt PLC is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom and maintains a U.S. headquarters in St. Louis, Missouri.

62. Defendant Mallinckrodt, LLC is a limited liability company organized and existing under the laws of the State of Delaware. Mallinckrodt, LLC is a wholly owned subsidiary of Mallinckrodt, Plc. Mallinckrodt, Plc and Mallinckrodt, LLC are collectively referred to as "Mallinckrodt." Mallinckrodt is engaged in the manufacture, promotion, and distribution of Roxicodone and Oxycodone among other drugs in Marshall County.

63. In 2017, The Department of Justice (DOJ) fined Mallinckrodt $35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements.[37]

64. Defendant Allergan Plc is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Defendant Actavis Plc acquired Defendant

[35] FDA News Release, "FDA Requests Removal of Opana ER for Risks Related to Abuse," *U.S. Food & Drug Administration*, 8 June 2017. Web. 10 Oct. 2017.

[36] *Id*.

[37] Press Release, "Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations," *U.S. Dept. of Justice*, 11 July 2017. Web. 16 Sept. 2017.

Allergan Plc in March 2015, and the combined company changed its name to Allergan Plc in January 2013. Before that, Defendant Watson Pharmaceuticals, Inc. acquired Defendant Actavis, Inc. in October 2012, and the combined company changed its name to Actavis, Inc. as of January 2013 and then Actavis Plc in October 2013.

65. Defendant Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of Defendant Allergan Plc (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.). Defendant Actavis Pharma, Inc. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey and was formerly known as Watson Pharma, Inc. Defendant Actavis LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Each of these defendants is owned by Defendant Allergan Plc, which uses them to market and sell its drugs in the United States. Defendant Allergan Plc exercises control over these marketing and sales efforts and profits from the sale of Allergan/Actavis products ultimately inure to its benefit. Allergan Plc, Actavis Plc, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. are referred to as "Actavis."

66. Actavis manufactures, promotes, sells, and distributes opioids, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana in the United States. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008, and began marketing Kadian in 2009.

67. Defendant AmerisourceBergen Drug Corporation ("AmerisourceBergen") is a Delaware corporation with its principal place of business located in Chesterbrook, Pennsylvania. AmerisourceBergen is the second largest pharmaceutical distributor in North America.

AmerisourceBergen does substantial business in the State of Indiana where it distributes pharmaceuticals in Marshall County.

68. Defendant Cardinal Health, Inc. ("Cardinal" or "Cardinal Health") is an Ohio Corporation with its principal place of business in Dublin, Ohio. In 2013, Cardinal paid a $34 million fine for failing to report suspicious orders of controlled substances. Cardinal does substantial business in the State of Indiana where it distributes pharmaceuticals in Marshall County.

69. Defendant McKesson Corporation ("McKesson") is a Delaware Corporation with its principal place of business located in San Francisco, California. McKesson is the largest pharmaceutical distributor in North America. McKesson delivers approximately one-third of all pharmaceuticals used in North America. McKesson does substantial business in Indiana where it distributes pharmaceuticals in Marshall County.

FACTUAL ALLEGATIONS

I. Opioids Are Addictive.

70. The pain-relieving properties of opium have long been recognized. So has the magnitude of its potential for abuse and addiction. Opioids are related to illegal drugs like opium and heroin.

71. During the Civil War, opioids gained popularity among doctors and pharmacists for their ability to reduce anxiety and relieve pain – particularly on the battlefield – and they were popularly used in a wide variety of commercial products ranging from pain elixirs to cough

suppressants to beverages. [38] By 1900, about 300,000 people were addicted to opioids in the United States,[39] and many doctors prescribed opioids solely to avoid patients' withdrawal.

72. Both the numbers of opioid addicts and the difficulty in weaning patients from opioids made clear their highly addictive nature. "By the 1920s, doctors were aware of the highly addictive nature of opioids and tried to avoid treating patients with them."[40]

73. Due to concerns about their addictive properties, opioids have been regulated at the federal level as controlled substances by the U.S. Drug Enforcement Administration ("DEA") since 1970.

74. "By the mid- and late-1970s . . . doctors had long been taught to avoid prescribing highly addictive opioids to patients."[41] Studies and articles from the 1970s and 1980s made clear the reasons to avoid opioids. Scientists observed negative outcomes from long-term opioid therapy in pain management programs; opioids' mixed record in reducing pain long-term and failure to improve patients' function; greater pain complaints as most patients developed tolerance to opioids; opioid patients' diminished ability to perform basic tasks; their inability to make use of complementary treatments like physical therapy due to the side effects of opioids; and addiction. Leading authorities discouraged, or even prohibited, using opioid therapy for chronic pain.

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[38] Moghe, Sonia, "Opioid History: From 'Wonder Drug' to Abuse Epidemic, *CNN.com*, Cable News Network, 14 Oct. 2016. Web. 24 Oct. 2017.

[39] Substance Abuse and Mental Health Services Administration, Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs, Treatment Improvement Protocol (TIP Services), No. 43 (2005).

[40] Moghe, Sonia, "Opioid History: From 'Wonder Drug' to Abuse Epidemic, *CNN.com*, Cable News Network, 14 Oct. 2016. Web. 24 Oct. 2017.

[41] *Id*.

75. In 1986, Dr. Portenoy, who later became Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York while serving as a top spokesperson for drug companies, published an article reporting that "[f]ew substantial gains in employment or social function could be attributed to the institution of opioid therapy."[42]

76. Writing in 1994, Dr. Portenoy described the prevailing attitudes regarding the dangers of long-term use of opioids:

> *The traditional approach to chronic non-malignant pain does not accept the long-term administration of opioid drugs.* This perspective has been justified by the perceived likelihood of tolerance, which would attenuate any beneficial effects over time, and the potential for side effects, worsening disability, and addiction. According to conventional thinking, the initial response to an opioid drug may appear favorable, with partial analgesia and salutary mood changes, but adverse effects inevitably occur thereafter. It is assumed that the motivation to improve function will cease as mental clouding occurs and the belief takes hold that the drug can, by itself, return the patient to a normal life. *Serious management problems are anticipated, including difficulty in discontinuing a problematic therapy and the development of drug seeking behavior induced by the desire to maintain analgesic effects, avoid withdrawal, and perpetuate reinforcing psychic effects. There is an implicit assumption that little separates these outcomes from the highly aberrant behaviors associated with addiction*.[43]

According to Dr. Portenoy, the foregoing problems could constitute "compelling reasons to reject long-term opioid administration as a therapeutic strategy in all but the most desperate cases of chronic nonmalignant pain."[44]

77. For all the reasons outlined by Dr. Portenoy, and in the words of one researcher from the University of Washington in 2012, and quoted by a Harvard researcher the same year,

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[42] Portenoy, R. & Foley, K., "Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 cases," 25(2) Pain 171 (1986).

[43] Portenoy, R., "Opioid Therapy for Chronic Nonmalignant Pain: Current Status," 1 Progress in Pain Res. & Mgmt., 247-287 (H.L. Fields and J.C. Liebeskind eds., 1994) (emphasis added).

[44] *Id*.

"it did not enter [doctors'] minds that there could be a significant number of chronic pain patients who were successfully managed with opioids, because if there were any, we almost never saw them."[45]

78. Discontinuing opioids after more than just a few weeks of therapy will cause most patients to experience withdrawal symptoms. These withdrawal symptoms include: severe anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, pain, and other serious symptoms, which may persist for months after a complete withdrawal from opioids, depending on how long the opioids were used.[46]

79. When under the continuous influence of opioids over time, patients grow tolerant to their analgesic effects. As tolerance increases, a patient typically requires progressively higher doses to obtain the same levels of pain reduction to which he has become accustomed – up to and including doses that are "frighteningly high."[47] At higher doses, the effects of withdrawal are more substantial leaving a patient at a much higher risk of addiction. A patient can take the opioids at the continuously escalating dosages to match pain tolerance and still overdose at recommended levels.

80. Opioids vary by duration. Long-acting opioids, such as Purdue's OxyContin and MS Contin, Janssen's Nucynta ER and Duragesic, Endo's Opana ER, and Actavis's Kadian, are designed to be taken once or twice daily and are purported to provide continuous opioid therapy

[45] Loeser, J., "Five Crises in Pain Management, Pain Clinical Updates," 2012; 20 (1):1–4 (cited by I. Kissin, Long-term opioid treatment of chronic nonmalignant pain: unproven efficacy and neglected safety?, 6 J. Pain Research 513, 514 (2013)).

[46] "Health Guide: Opiate Withdrawal," *The New York Times*. Web. 24 Oct. 2017.

[47] Katz, M., "Long-term Opioid Treatment of Nonmalignant Pain: A Believer Loses His Faith," 170(16) Archives of Internal Med. 1422 (2010).

for, in general, 12 hours. Short-acting opioids, such as Cephalon's Actiq and Fentora, are designed to be taken in addition to long-acting opioids to address "episodic pain" and provide fast-acting, supplemental opioid therapy lasting approximately 4 to 6 hours.

81. In 2013, the FDA warned of the "grave risks" of opioids, including "addiction, overdose, and even death." The FDA further warned, "[e]ven proper use of opioids under medical supervision can result in life- threatening respiratory depression, coma, and death." Because of those grave risks, the FDA said that long-acting or extended release opioids "should be used only when alternative treatments are inadequate."[48]

82. The facts on which the FDA relied were well known to Manufacturer Defendants in the 1990s when their deceptive marketing began.

II. No Scientific Evidence Supports Long Term Use of Opioids.

83. There is no scientific evidence supporting the safety or efficacy of opioids for long-term use.[49] Manufacturer Defendants are aware of the lack of such scientific evidence. While promoting opioids to treat chronic pain, Manufacturer Defendants failed to disclose the lack of evidence to support their use long-term and have failed to disclose the substantial scientific evidence that chronic opioid therapy makes patients sicker.

[48] Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. *Physicians for Responsible Opioid Prescribing,* Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013) (emphasis in original).

[49] *See, e.g.*, S. Quinones, *Dreamland* 92 (2015) (noting that researchers other than Manufacturer Defendants' KOLs "had been issuing papers saying that many chronic-pain patients using opiate invariably ended up addicted").

84. There are no controlled studies of the use of opioids beyond 12 weeks, and no evidence that opioids improve patients' pain and function long-term.[50] A 2007 systematic review of opioids for back pain concluded that opioids have limited, if any, efficacy for back pain and that evidence did not allow judgments regarding long- term use.[51]

85. Substantial evidence exists that opioid drugs are ineffective to treat chronic pain, and actually worsen patients' health. A 2006 study-of-studies found that opioids as a class did not demonstrate improvement in functional outcomes over other non-addicting treatments.[52]

86. Increasing duration of opioid use is strongly associated with an increasing prevalence of mental health conditions (including depression, anxiety, post-traumatic stress disorder, or substance abuse), increased psychological distress, and greater health care utilization.[53]

87. While opioids may work acceptably well for a while, when used on a long term basis, patient function declines, as does general health, mental health, and social function. Over

[50] *See, e.g.*, Dowell, Deborah MD et al., "CDC Guideline for Prescribing Opioids for Chronic Pain," *Centers for Disease Control and Prevention*, 18 Mar. 2016. Web. 24 Oct. 2017.

[51] Martell, BA. et al., "Systematic Review: Opioid Treatment for Chronic Back Pain: Prevalence, Efficacy, and Association with Addiction," Ann Intern Med. 2007 Jan 16;146(2):116-27.

[52] Furlan, AD. et al., "Opioids for Chronic Noncancer Pain: a Meta-Analysis of Effectiveness and Side Effects," CMAJ. 2006 May 23;174(11):1589-94. This same study revealed that efficacy studies do not typically include data on opioid addiction. In many cases, patients who may be more prone to addiction are pre-screened out of the study pool. This does not reflect how doctors actually prescribe the drugs, because even patients who have past or active substance use disorders tend to receive higher doses of opioids. *See* Seal, Karen et al., "Association of Mental Health Disorders with Prescription Opioids and High- Risk Opioids in US Veterans of Iraq and Afghanistan," JAMA. 2012;307(9):940-947.

[53] "Effects of Opioid Abuse on Your Mental Health," *Disorders.org*. Web. 24 Oct. 2017.

time, even high doses of potent opioids often fail to control pain, and patients exposed to such doses cannot function normally.[54]

88. Studies of the use of opioids long-term for chronic lower back pain cannot demonstrate an improvement in patients' function. Instead, research consistently shows that long-term opioid therapy for patients who have lower back injuries does not cause patients to return to work or physical activity. This is due partly to addiction and other side effects.[55]

III. Manufacturer Defendants' Scheme to Realize Blockbuster Profits.

89. Before Manufacturer Defendants began the marketing campaign that is the subject of this complaint, generally accepted standards of medical practice dictated that opioids should only be used short-term, for instance, for acute pain, pain relating to recovery from surgery, or for cancer or palliative care.

90. Manufacturer Defendants promoted that pain should be treated by taking long-acting opioids continuously and supplementing them by also taking short-acting, rapid- onset opioids for episodic pain.

91. "For generations, physicians have been taught that opioid painkillers are highly addictive and should be used sparingly and primarily in patients near death."[56]

92. The market for short-term pain relief, however, is significantly more limited than the market for long-term chronic pain relief. Manufacturer Defendants recognized that if they

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[54] *See* Rubenstein, Andrea, "Are we Making Pain Patients Worse?" *Sonoma Medicine*. Web. 25 Oct. 2017.

[55] Freud, J. et al., "How Effective are Opioids for Chronic Low Back Pain?," J. Fam. Pract., 64(9):584-585 (Sept. 2015).

[56] Ryan, H. et al., "OxyContin goes Global—'We're only just getting started'," *The Los Angeles Times*, 18 Dec. 2016. Web. 24 Oct. 2017.

could sell opioids not just for short term pain relief but also for long-term chronic pain relief, they could achieve blockbuster levels of sales and their profits:

> From the start, Purdue promoted OxyContin far beyond the cancer and postsurgical patients . . . The company aimed to convince doctors to aggressively treat noncancer pain, and prescribe OxyContin for moderate pain lasting more than a few days. OxyContin ought to be used for bad backs, knee pain, tooth extraction, headaches, fibromyalgia, as well as football, hockey, and dirt-bike injuries, broken bones, and, of course, after surgery. **This was a vast new market for an opiate painkiller. U.S. back pain patients alone numbered some thirty-five million people; the total number of cancer patients was a fifth of that.**[57]

93. Cephalon promoted its Actiq for migraines, sickle-cell pain, and injuries, although the FDA had approved its use only for cancer pain.[58] Cephalon pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs, and agreed to pay $425 million.[59]

94. Janssen promoted its Ultracet for everyday chronic pain, distributing posters to doctor's offices that showed people in active professions with the tagline "Pain doesn't fit their schedules."[60]

95. Endo, maker of Opana, Percocet, and Percodan, distributed a patient education publication that said withdrawal symptoms and increased tolerance to opioids are not the same as addiction: "Addicts take opioids for other reasons, such as unbearable emotional problems."[61]

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[57] S. Quinones, *Dreamland* 126–27 (2015).

[58] J. Temple, *American Pain* 49 (2015).

[59] Press Release, "Biopharmaceutical Company, Cephalon, to Pay $425 Million & Enter Plea to Resolve Allegations of Off-Label Marketing," *U.S. Dept. of Justice*, 29 Sept. 2008. Web. 24 Oct. 2017.

[60] J. Temple, *American Pain* 49 (2015).

[61] *Id.*

96. Internal Purdue documents show that OxyContin was developed to cure its financial problems. In the late 1980s, the patent on its main source of revenue, a morphine pill for cancer patients call MS Contin, was running out. Executives "anticipated a massive loss of revenue as generic versions drove down the price of MS Contin" so a 1990 memo stated that "other controlled-release opioids must be considered."[62] It certainly worked—the success of OxyContin brought a whole new level of wealth to the Sackler family that owns Purdue. Forbes magazine last year estimated the Sacklers' worth at $14 billion, which put the family ahead of American dynasties such as the Mellons and Rockefellers.[63]

97. Manufacturer Defendants knew that to increase their profits from the sale of opioids they would need to convince doctors and patients that long-term opioid therapy was safe and effective. Manufacturer Defendants needed to persuade physicians to abandon their long-held apprehensions about prescribing opioids, and instead to prescribe opioids for durations previously understood to be unsafe.

98. An internal Purdue document admits that the company did "not want to niche OxyContin just for cancer pain," so it spent $207 million on the launch of OxyContin and doubled its sales force to 600.[64]

99. Manufacturer Defendants knew that their goal of increasing profits by promoting the prescription of opioids for chronic pain would lead directly to an increase in health care costs for patients, health care insurers, and cities and counties.

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[62] Ryan, Harriet, et al., "'You want a Description of Hell?' Oxycontin's 12-Hour Problem," *The Los Angeles Times*, 5 May 2016. Web. 25 Oct. 2017.

[63] *Id.*

[64] *Id.*

100. Marshalling help from consultants and public relations firms, Manufacturer Defendants developed and executed a common strategy to reverse the long-settled understanding of the relative risks and benefits of chronic opioid therapy. Unable to add to the collective body of legitimate medical knowledge concerning the best ways to treat pain and improve patient quality of life, however, Manufacturer Defendants instead sought to distort medical and public perception of existing scientific data.

101. Manufacturer Defendants, collectively and individually, poured vast sums of money into generating articles, continuing medical education courses ("CMEs"), and other "educational" materials, conducting sales visits to individual doctors, and supporting a network of professional societies and advocacy groups, which was intended to, and which did, create a new but fake "consensus" supporting the long-term use of opioids.

IV. Manufacturer Defendants Use "Unbranded" Marketing to Evade Laws and Regulations.

102. Drug companies' promotional activity can be branded or unbranded; unbranded marketing refers not to a specific drug, but more generally to a disease state or treatment. By using unbranded communications, drug companies can evade the extensive regulatory framework governing branded communications because unbranded advertising isn't regulated by the FDA.[65]

[65] *See, e.g., In re Testosterone Replacement Therapy Prod. Liab. Litig. Coordinated Pretrial Proceedings*, No. 14 C 1748, 2017 WL 1836443, 92 UCC Rep. Serv. 2d 729 (N.D. Ill. May 8, 2017) ("Unbranded advertisements do not require FDA review because the FDA considers unbranded advertisements educational rather than promotional").

103. The federal Food, Drug, and Cosmetic Act ("FDCA") prohibits the sale in interstate commerce of drugs that are "misbranded." A drug is "misbranded" if it lacks "adequate directions for use" or if the label is false or misleading "in any particular."

104. Manufacturer Defendants generally avoided using branded advertisements to spread their deceptive messages and claims regarding opioids to evade regulatory review.

105. Instead, Manufacturer Defendants disseminated much of their false, misleading, imbalanced, and unsupported statements through unregulated, unbranded marketing materials – materials that generally promoted opioid use but did not name a specific opioid while doing so. Through these unbranded materials, Manufacturer Defendants presented information and instructions concerning opioids generally that were false and misleading.

106. By acting through third parties, Manufacturer Defendants could give the false appearance that their messages reflected the views of independent third parties. Later, Manufacturer Defendants cited to these sources as "independent" corroboration of their own statements. Further, as one physician adviser to Manufacturer Defendants noted, third-party documents had not only greater credibility, but also broader distribution, as doctors did not "push back" at having materials, for example, from the non-profit American Pain Foundation ("APF") on display in their offices, as they would with drug company materials.

107. As part of their marketing scheme, Manufacturer Defendants spread and validated their deceptive messages through the following unbranded scheme ("the Unbranded Scheme"): (i) so-called "key opinion leaders" (i.e., physicians who influence their peers' medical practice, including but not limited to prescribing behavior) ("KOLs"), who wrote favorable journal articles and delivered supportive CMEs; (ii) a body of biased and unsupported, purportedly scientific, literature; (iii) treatment guidelines; (iv) CMEs; and (v) unbranded patient education

materials disseminated through groups purporting to be patient-advocacy and professional organizations ("Front Groups"), which exercised their influence both directly and indirectly through Defendant-controlled KOLs who served in leadership roles in these organizations.

108. Manufacturer Defendants disseminated many of their false, misleading, imbalanced and unsupported messages through the Unbranded Scheme because those messages appeared to uninformed observers to be independent. Through unbranded materials, Manufacturer Defendants presented information and instructions concerning opioids generally that were false and misleading.

109. Even where such unbranded messages were disseminated through third-parties, Manufacturer Defendants adopted these messages as their own when they cited to, edited, approved, and distributed such materials knowing they were false, misleading, unsubstantiated, unbalanced, and incomplete. Manufacturer Defendants' sales representatives distributed third-party marketing material to Manufacturer Defendants' target audience that was deceptive.

110. Manufacturer Defendants took an active role in guiding, reviewing, and approving many of the misleading statements issued by third parties, ensuring that Manufacturer Defendants were consistently in control of their content. By funding, directing, editing, and distributing these materials, Manufacturer Defendants exercised control over their deceptive messages and acted in concert with these third parties fraudulently to promote the use of opioids for the treatment of to treat chronic pain.

111. The unbranded marketing materials that Manufacturer Defendants assisted in creating and distributing did not disclose the risks of addiction, abuse, misuse, and overdose, and affirmatively denied or minimized those risks.

112. In 2007, multiple States sued Purdue for engaging in unfair and deceptive practices in its marketing, promotion, and sale of OxyContin. Certain states settled their claims in a series of Consent Judgments that prohibited Purdue from making misrepresentations in the promotion and marketing of OxyContin in the future. By using indirect and unbranded marketing strategies, however, Purdue intentionally circumvented these restrictions.

A. Manufacturer Defendants' KOLs.

113. After Purdue launched OxyContin in the U.S. in 1996, the company ran training seminars for KOLs in the pain field. Doctors were invited to all-expenses paid weekends in resort locations like Boca Raton, Florida, and Scottsdale, Arizona. The company found that doctors who attended seminars in 1996 wrote more than twice as many prescriptions as those who didn't, according to a company analysis.[66] Several thousand of these specialists signed on to the Purdue "speakers bureau," which paid them to make speeches about opioids at medical conferences and at hospitals.

114. All Manufacturer Defendants cultivated a select circle of doctors chosen and sponsored by Manufacturer Defendants solely because they favored the aggressive treatment of chronic pain with opioids. Pro-opioid doctors have been at the hub of Manufacturer Defendants' promotional efforts, presenting the appearance of unbiased and reliable medical research supporting the broad use of opioid therapy for chronic pain. These pro-opioid doctors have written, consulted on, edited, and lent their names to books and articles, and given speeches and CMEs supportive of opioid therapy for chronic pain. They have served on committees that developed treatment guidelines that strongly encouraged the use of opioids to treat chronic pain

[66] Ryan, H. et al., "OxyContin goes Global—'We're only just getting started'," *The Los Angeles Times*, 18 Dec. 2016. Web. 24 Oct. 2017.

and on the boards of purportedly independent pro-opioid advocacy groups and professional societies that develop, select, and present CMEs. Manufacturer Defendants were able to exert control of each of these modalities through their KOLs.

115. In return for their pro-opioid advocacy, Manufacturer Defendants' KOLs received money, prestige, recognition, research funding, and avenues to publish.

116. Manufacturer Defendants cited and promoted their KOLs and studies or articles by their KOLs to broaden the chronic opioid therapy market. By contrast, Manufacturer Defendants did not support, acknowledge, or disseminate the publications of doctors critical of using chronic opioid therapy.

117. Manufacturer Defendants carefully vetted their KOLs to ensure that they were likely to remain on-message and supportive of their agenda. Manufacturer Defendants also kept close tabs on the content of the materials published by these KOLs.

118. In their promotion of using opioids to treat chronic pain, Manufacturer Defendants' KOLs knew that their statements were false and misleading, or they recklessly disregarded the truth, but they continued to publish their misstatements to benefit themselves and Manufacturer Defendants.

B. Manufacturer Defendants' Corrupt Scientific Literature.

119. Rather than test the safety and efficacy of opioids for long- term use, Manufacturer Defendants led physicians, patients, and the public to believe that such tests had already been done. Manufacturer Defendants created a body of false, misleading, and unsupported medical and popular literature about opioids that (a) understated the risks and overstated the benefits of long-term use; (b) appeared to result from independent, objective research; and (c) was likely to shape the perceptions of prescribers, patients, and payors. This

literature was marketing material intended to persuade doctors and consumers that the benefits of long- term opioid use outweighed the risks.

120. To accomplish their goal, Manufacturer Defendants—sometimes through third-party consultants and/or front groups—commissioned, edited, and arranged for the placement of favorable articles in academic journals.

121. Manufacturer Defendants' plans for these materials did not originate in the departments responsible for research, development, or any other area that would have specialized knowledge about the drugs and their effects on patients; rather, they originated in Manufacturer Defendants' marketing departments and with Manufacturer Defendants' marketing and public relations consultants.

122. In these materials, Manufacturer Defendants (or their surrogates) often claimed to rely on "data on file" or presented posters, neither of which are subject to peer review. Still, Manufacturer Defendants presented these materials to the medical community as scientific articles or studies, although Manufacturer Defendants' materials were not based on reliable data and subject to the scrutiny of experts in the field.

123. Manufacturer Defendants also made sure that favorable articles were disseminated and cited widely in the medical literature, even when Manufacturer Defendants knew that the articles distorted the significance or meaning of the underlying study.

124. Most notably, Purdue frequently cited a 1980 item in the well-respected New England Journal of Medicine, J. Porter & H. Jick, *Addiction Rare in Patients Treated with Narcotics*, 302 (2) New Eng. J. Med. 123 (1980) ("Porter & Jick Letter"), in a manner that makes it appear that the item reported the results of a peer reviewed study. It is also cited in two CME programs sponsored by Endo.

125. Manufacturer Defendants and those acting on their behalf failed to reveal this "article" is actually a letter to the editor, not a study, much less a peer-reviewed study. The one-paragraph letter, reproduced in full below, states that the authors only examined their files of hospitalized patients who had received opioids.

ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS

To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients[1] who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,[2] Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

JANE PORTER
HERSHEL JICK, M.D.
Boston Collaborative Drug Surveillance Program
Boston University Medical Center
Waltham, MA 02154

1. Jick H, Miettinen OS, Shapiro S, Lewis GP, Siskind Y, Slone D. Comprehensive drug surveillance. JAMA. 1970; 213:1455-60.
2. Miller RR, Jick H. Clinical effects of meperidine in hospitalized medical patients. J Clin Pharmacol. 1978; 18:180-8.

126. The patients referred to in the letter were all treated prior to the letter, which was published in 1980. Because of standards of care prior to 1980, the treatment of those patients with opioids would have been limited to acute or end-of-life situations, not chronic pain. The letter notes that, when these patients' records were reviewed, the authors found almost no references to signs of addiction, though there is no indication that caregivers were instructed to look for, assess, or document signs of addiction. Nor is there any indication whether the patients were followed after they were discharged from the hospital or, if they were, for how long. None of these serious limitations was disclosed when Manufacturer Defendants and those acting on their behalf cited the letter, typically as the sole scientific support for the proposition that opioids are rarely addictive.

127. "That single paragraph, buried in the back pages of the *New England Journal of Medicine*, was mentioned, lectured on, and cited until it emerged transformed into, in the words of one textbook, a 'landmark report' that 'did much to counteract' fears of addiction in pain patients treated with opiates."[67]

128. Dr. Jick has complained that his letter has been distorted and misused. Dr. Jick states that the letter "does *not* speak to the level of addiction in outpatients who take these drugs for chronic pain."[68]

129. Manufacturer Defendants worked to not only create and promote favorable studies in the literature, but to discredit or suppress negative information. Manufacturer Defendants' studies and articles often targeted articles that contradicted Manufacturer Defendants' claims or raised concerns about chronic opioid therapy. To do so, Manufacturer Defendants – often with the help of third- party consultants – used a broad range of media to get their message out, including negative review articles, letters to the editor, commentaries, case-study reports, and newsletters.

130. Manufacturer Defendants' strategy – to plant and promote supportive literature and then to cite the pro-opioid evidence in their promotional materials, while failing to disclose evidence that contradicted those claims – flatly contradicted their legal obligations. The strategy was intended to, and did, distort prescribing patterns by distorting the truth regarding the risks and benefits of opioids for chronic pain relief.

[67] S. Quinones, *Dreamland* 108 (2015).

[68] *Id*. (emphasis in original).

C. Manufacturer Defendants' Misuse of Treatment Guidelines.

131. Treatment guidelines have been particularly important in securing acceptance for chronic opioid therapy. They are relied upon by doctors, especially the general practitioners and family doctors targeted by Manufacturer Defendants, who are generally not experts, and who generally have no special training, in the treatment of chronic pain. Treatment guidelines not only directly inform doctors' prescribing practices, but also are cited throughout scientific literature and relied on by third-party payors in determining whether they should pay for treatments for specific indications.

1. FSMB

132. The Federation of State Medical Boards ("FSMB") is a trade organization representing the various state medical boards in the United States. The state boards that comprise the FSMB membership have the power to license doctors, investigate complaints, and discipline physicians. The FSMB finances opioid- and pain-specific programs through grants from Manufacturer Defendants.

133. Since 1998, the FSMB has been developing treatment guidelines for using opioids to treat pain. The 1998 version, Model Guidelines for the Use of Controlled Substances for the Treatment of Pain ("1998 Guidelines") was produced "in collaboration with pharmaceutical companies" and taught not that opioids could be appropriate in limited cases after other treatments had failed, but that opioids were "essential" for treatment of chronic pain, including as a first prescription option.

134. A 2004 iteration of the 1998 Guidelines and the 2007 book, Responsible Opioid Prescribing, also made the same claims as the 1998 Guidelines. These guidelines were posted online and were available to and intended to reach physicians nationwide, including in Marshall County.

135. The publication of Responsible Opioid Prescribing was backed largely by drug manufacturers. 163,131 copies of Responsible Opioid Prescribing were distributed by state medical boards (and through the boards, to practicing doctors). The FSMB website describes the book as the "leading continuing medication (CME) activity for prescribers of opioid medications."

136. Manufacturer Defendants relied on 1998 Guidelines to convey the alarming message that "under-treatment of pain" would result in official discipline, but no discipline would result if opioids were prescribed as part of an ongoing patient relationship and prescription decisions were documented. FSMB turned doctors' fear of discipline on its head: doctors, who used to believe that they would be disciplined if their patients became addicted to opioids, were taught instead that they would be punished if they failed to prescribe opioids to their patients with chronic pain.

2. AAPM/APS Guidelines

137. American Academy of Pain Medicine ("AAPM") and the American Pain Society ("APS") are professional medical societies, each of which received substantial funding from Manufacturer Defendants from 2009 to 2013. In 1997, AAPM issued a "consensus" statement that endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low.[69] The Chair of the committee that issued the statement, Dr. J. David Haddox, was at the time a paid speaker for Purdue. The sole consultant to the committee was Dr. Portenoy. The consensus statement, which also formed the foundation of the 1998 Guidelines, was published on the AAPM's website.

[69] "The Use of Opioids for the Treatment of Chronic Pain," *American Academy of Pain Medicine & American Pain Society* (1997). Web. 25 Oct. 2017.

138. AAPM and APS issued their own guidelines in 2009 ("2009 Guidelines") and continued to recommend the use of opioids to treat chronic pain. Fourteen of the 21 panel members who drafted the 2009 Guidelines, including KOLs Dr. Portenoy and Dr. Fine, received financial support from Manufacturer Defendants Janssen, Cephalon, Endo, and Purdue.

139. The 2009 Guidelines promote opioids as "safe and effective" for treating chronic pain and conclude that the risk of addiction is manageable for patients regardless of past abuse histories. The 2009 Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids; they were reprinted in the Journal of Pain, have been cited hundreds of times in academic literature, were disseminated in Marshall County during the relevant time period, and were and are available online.

140. Manufacturer Defendants widely cited and promoted the 2009 Guidelines without disclosing the lack of evidence to support their conclusions.

3. Guidelines Not Supported by Manufacturer Defendants

141. The extent of Manufacturer Defendants' influence on treatment guidelines is demonstrated because independent guidelines – the authors of which did not accept drug company funding – reached very different conclusions.

142. The 2012 Guidelines for Responsible Opioid Prescribing in Chronic Non- Cancer Pain, issued by the American Society of Interventional Pain Physicians ("ASIPP"), warned that "[t]he recent revelation that the pharmaceutical industry was involved in the development of opioid guidelines as well as the bias observed in the development of many of these guidelines illustrate that the model guidelines are not a model for curtailing controlled substance abuse and may, in fact, be facilitating it." ASIPP's Guidelines further advise that "therapeutic opioid use, specifically in high doses over long periods of time in chronic non-cancer pain starting with

acute pain, not only lacks scientific evidence, but is in fact associated with serious health risks including multiple fatalities, and is based on emotional and political propaganda under the guise of improving the treatment of chronic pain." ASIPP recommends long-acting opioids in high doses only "in specific circumstances with severe intractable pain" and only when coupled with "continuous adherence monitoring, in well-selected populations, in conjunction with or after failure of other modalities of treatments with improvements in physical and functional status and minimal adverse effects."[70]

143. Similarly, the 2011 Guidelines for the Chronic Use of Opioids, issued by the American College of Occupational and Environmental Medicine, recommend against the "routine use of opioids in the management of patients with chronic pain," finding "at least moderate evidence that harms and costs exceed benefits based on limited evidence."[71]

144. The Clinical Guidelines on Management of Opioid Therapy for Chronic Pain, issued by the U.S. Department of Veterans Affairs ("VA") and Department of Defense ("DOD") in 2010, notes the lack of solid evidence-based research on the efficacy of long-term opioid therapy.[72]

[70] Manchikanti, L. et al., "American Society of Interventional Pain Physicians (ASIPP) Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain: Part 1, Evidence Assessment," 15 Pain Physician (Special Issue) S1-S66; Part 2 – Guidance, 15 Pain Physician (Special Issue) S67-S116 (2012).

[71] "Guidelines for the Chronic Use of Opioids," *American College of Occupational and Environmental Medicine (ACOEM)*, 2011.

[72] "VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain," *The Dept. of Veterans Affairs* and *The Dept. of Defense*, p. 5, May 2010.

D. Manufacturer Defendants' Misuse of CMEs.

145. Doctors must attend a certain number and, often, type of CME programs each year as a condition of their licensure. These programs are delivered in person, often in connection with professional organizations' conferences, and online, or through written publications. Doctors rely on CMEs not only to satisfy licensing requirements, but also to get information on new developments in medicine or to deepen their knowledge in specific areas of practice. Because CMEs typically are taught by KOLs highly respected in their fields, and are thought to reflect these physicians' medical expertise, they can be especially influential with doctors.

146. The countless doctors and other health care professionals who participate in accredited CMEs constitute an enormously important audience for opioid reeducation. As one target, Manufacturer Defendants aimed to reach general practitioners, whose broad area of practice and lack of expertise and specialized training in pain management made them particularly dependent upon CMEs and especially susceptible to Manufacturer Defendants' deceptions.

147. Manufacturer Defendants sponsored CMEs delivered thousands of times, promoting chronic opioid therapy and supporting and disseminating the deceptive and biased messages described in this Complaint. These CMEs, while often generically titled to relate to the treatment of chronic pain, focus on opioids to the exclusion of alternative treatments, inflate the benefits of opioids, and frequently omit or downplay their risks and adverse effects.

148. The American Medical Association ("AMA") has recognized that support from drug companies with a financial interest in the content being promoted "creates conditions in which external interests could influence the availability and/or content" of the programs and

urges that "[w]hen possible, CME[s] should be provided without such support or the participation of individuals who have financial interests in the education subject matter."[73]

149. Physicians from Marshall County attended or reviewed Manufacturer Defendants' sponsored CMEs during the relevant time period and were misled by them.

150. By sponsoring CME programs put on by Front Groups like APF, AAPM and others, Manufacturer Defendants gained messages favorable to them, as these organizations depended on Manufacturer Defendants for other projects. The sponsoring organizations hired pro-opioid KOLs to give talks that supported chronic opioid therapy. Defendant-driven content in these CMEs had a direct and immediate effect on prescribers' views on opioids. Producers of CMEs and Manufacturer Defendants measure the effects of CMEs on prescribers' views on opioids and their absorption of specific messages, confirming the strategic marketing purpose in supporting them.

E. Manufacturer Defendants' Misuse of Patient Education Materials and Front Groups.

151. Pharmaceutical industry marketing experts see patient-focused advertising, including direct-to-consumer marketing, as particularly valuable in "increas[ing] market share . . . by bringing awareness to a particular disease that the drug treats."[74] The United States and New Zealand are the only two developed nations that permit direct-to-consumer marketing.[75] Physicians are more likely to prescribe a drug if a patient specifically requests it, and physicians'

[73] "Opinion 9.0115 - Financial Relationships with Industry in CME, *American Medical Association (AMA)*, Nov. 2011.

[74] Johar, Kanika, "An Insider's Perspective: Defense of the Pharmaceutical Industry's Marketing Practices," 76 Albany L. Rev. 299, 308 (2013).

[75] "Keeping Watch Over Direct-to-Consumer Ads," *U.S. Food & Drug Administration*, 16 Oct. 2017. Web. 25 Oct. 2017.

willingness to acquiesce to such patient requests holds true even for opioids and for conditions for which they are not approved.[76] Recognizing this phenomenon, Manufacturer Defendants use relationships with Front Groups to engage in largely unbranded patient education about opioid treatment for chronic pain.

152. Manufacturer Defendants entered into arrangements with numerous Front Groups to promote opioids. These organizations depend upon Manufacturer Defendants for significant funding and, sometimes, for their survival. They were involved not only in generating materials and programs for doctors and patients that supported chronic opioid therapy, but also in assisting Manufacturer Defendants' marketing in other ways—for example, responding to negative articles and advocating against regulatory changes that would constrain opioid prescribing. They developed and disseminated pro-opioid treatment guidelines; conducted outreach to groups targeted by Manufacturer Defendants, such as veterans and the elderly; and developed and sponsored CMEs that focused exclusively on use of opioids to treat chronic pain. Manufacturer Defendants funded these Front Groups to ensure supportive messages from these seemingly neutral and credible third parties, and their funding did, in fact, achieve that goal.

1. American Pain Foundation

153. The most prominent of Manufacturer Defendants' Front Groups was the American Pain Foundation ("APF"), which received more than $10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012.

[76] In one study, for example, nearly 20% of sciatica patients requesting oxycodone received a prescription for it, compared with 1% of those making no specific request. McKinlay, John B. et al., "Effects of Patient Medication Requests on Physician Prescribing Behavior" Results of a Factorial Experiment," Med Care. 2014 Apr; 52(4): 294–299.

154. APF issued purported "education guides" for patients, the news media, and policymakers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction. APF also engaged in a significant multimedia campaign – through radio, television and the internet – to "educate" patients about their "right" to pain treatment with opioids. All of the programs and materials were intended to, and did, reach a national audience, including residents of Marshall County.

155. By 2011, APF depended on incoming grants from Manufacturer Defendants Purdue, Cephalon, Endo, and others. APF board member, Dr. Portenoy, explained the lack of funding diversity was one of the biggest problems at APF.

156. APF held itself out as an independent patient advocacy organization, yet engaged in grassroots lobbying against various legislative initiatives that might limit opioid prescribing. In reality, APF functioned largely as an advocate for the interests of Manufacturer Defendants, not patients.

157. APF operated in close collaboration with Manufacturer Defendants. APF submitted grant proposals seeking to fund activities and publications suggested by Manufacturer Defendants. APF also assisted in marketing projects for Manufacturer Defendants.

158. The close relationship between APF and Manufacturer Defendants demonstrates APF's clear lack of independence in its finances, management, and mission and its willingness to allow Manufacturer Defendants to control its activities and messages supports an inference that each Manufacturer Defendant that worked with it could exercise editorial control over its publications.

159. In May 2012, the U.S. Senate Finance Committee investigated APF to determine the links, financial and otherwise, between the organization and the manufacturers of opioid

painkillers. Within days of being targeted by the Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF then "cease[d] to exist, effective immediately."[77]

2. The American Academy of Pain Medicine

160. The American Academy of Pain Medicine ("AAPM"), with the assistance, prompting, involvement, and funding of Manufacturer Defendants, issued improper opioid treatment guidelines and sponsored and hosted CMEs essential to Manufacturer Defendants' deceptive marketing scheme.

161. AAPM received over $2.2 million in funding since 2009 from opioid manufacturers. AAPM maintained a corporate relations council, whose members paid $25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event – its annual meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual event as an "exclusive venue" for offering CMEs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Manufacturer Defendants Endo, Purdue, and Cephalon were members of the council and presented deceptive programs to doctors who attended this annual event.

162. The conferences sponsored by AAPM heavily emphasized CME sessions on opioids—37 out of roughly 40 at one conference alone. AAPM's presidents have included top industry-supported KOLs, Dr. Fine, Dr. Portenoy, and Dr. Webster. Dr. Webster was elected

[77] Ornstein, Charles et al., "Senate Panel Investigates Drug Companies ties to Pain Groups," *The Washington Post*, 8 May 2012. Web. 25 Oct. 2017.

president of AAPM while under a DEA investigation. Another past AAPM president, Dr. Scott Fishman, stated that he would place the organization "at the forefront" of teaching that "the risks of addiction are … small and can be managed."

163. AAPM's staff understood that they and their industry funders were engaged in a common task. Manufacturer Defendants could influence AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization.

V. Manufacturer Defendants Acted in Concert with KOLs and Front Groups in the Creation, Promotion, and Control of Unbranded Marketing.

164. Like cigarette makers, which engaged in an industry-wide effort to misrepresent the safety and risks of smoking, Manufacturer Defendants worked with each other and with the Front Groups and KOLs they funded and directed to carry out a common scheme to deceptively market opioids by misrepresenting the risks, benefits, and superiority of opioids to treat chronic pain.

165. Manufacturer Defendants acted through and with the same network of Front Groups, funded the same KOLs, and often used the same language and format to disseminate the same deceptive messages regarding the appropriate use of opioids to treat chronic pain. Although participants knew this information was false and misleading, these misstatements were disseminated nationwide, including to Marshall County prescribers and patients.

166. One vehicle for Manufacturer Defendants' marketing collaboration was Pain Care Forum ("PCF"). PCF began in 2004 as an APF project with the stated goals of offering "a setting where multiple organizations can share information" and "promote and support taking collaborative action regarding federal pain policy issues." APF President Will Rowe described the forum as "a deliberate effort to positively merge the capacities of industry, professional associations, and patient organizations."

167. PCF comprises representatives from opioid manufacturers and distributors (including Cephalon, Endo, Janssen, and Purdue); doctors and nurses in the field of pain care; professional organizations (including AAPM, APS, and American Society of Pain Educators); patient advocacy groups (including APF and American Chronic Pain Association ("ACPA")); and other similar organizations, almost all of which received substantial funding from Manufacturer Defendants.

168. PCF, for example, developed and disseminated "consensus recommendations" for a Risk Evaluation and Mitigation Strategy ("REMS") for long-acting opioids that the FDA mandated in 2009 to communicate the risks of opioids to prescribers and patients.[78] This was critical because a REMS that went too far in narrowing the uses or benefits or highlighting the risks of chronic opioid therapy would undermine Manufacturer Defendants' marketing efforts. The recommendations claimed that opioids were "essential" to the management of pain, and that the REMS "should acknowledge the importance of opioids in the management of pain and should not introduce new barriers." Manufacturer Defendants worked with PCF members to limit the reach and manage the message of the REMS, which enabled them to maintain, not undermine, their deceptive marketing of opioids for chronic pain.

VI. Manufacturer Defendants' Misrepresentations.

169. Manufacturer Defendants, through their own marketing efforts and publications and through their sponsorship and control of patient advocacy and medical societies and projects, caused deceptive materials and information to be placed into the marketplace, including to prescribers, patients, and payors in Marshall County. These promotional messages were intended

[78] The FDA can require a drug maker to develop a REMS—which could entail (as in this case) an education requirement or distribution limitation—to manage serious risks associated with a drug.

to and encouraged patients to ask for, doctors to prescribe, and payors to pay for chronic opioid therapy.

170. Doctors are the gatekeepers for all prescription drugs so, not surprisingly, Manufacturer Defendants focused the bulk of their marketing efforts, and their multi-million dollar budgets, on the professional medical community. Particularly because of barriers to prescribing opioids, which are regulated as controlled substances, Manufacturer Defendants knew doctors would not treat patients with common chronic pain complaints with opioids unless doctors were persuaded that opioids had real benefits and minimal risks. Accordingly, Manufacturer Defendants did not disclose to prescribers, patients or the public that evidence to support their promotional claims was inconclusive, non-existent or unavailable. Rather, each Manufacturer Defendant disseminated misleading and unsupported messages that caused the target audience to believe those messages were corroborated by scientific evidence. As a result, Marshall County doctors prescribed opioids long-term to treat chronic pain – something that most never would have considered prior to Manufacturer Defendants' campaign.

171. Drug company marketing materially impacts doctors' prescribing behavior.[79] Doctors rely on drug companies to provide them with truthful information about the risks and benefits of their products, and they are influenced by their patients' requests for particular drugs.

[79] *See, e.g.*, Manchanda, P. & Chintagunta, P.K. Marketing Letters (2004) 15: 129; Larken, Ian et al., "Restrictions on Pharmaceutical Detailing Reduced Off-Label Prescribing of Antidepressants and Antipsychotics in Children," *Health Affairs* 33, no.6 (2014):1014-1023 (finding academic medical centers that restricted direct promotion by pharmaceutical sales representatives resulted in a 34% decline in on-label use of promoted drugs). *See also* Van Zee, Art, "The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy." *American Journal of Public Health* 99.2 (2009): 221–227. *PMC*. (noting an increase of OxyContin prescriptions from 670,000 annually in 1997 to about 6.2 million in 2002 and an approximate doubling of Purdue's internal sales force from 1996 to 2000.)

172. Manufacturer Defendants spent millions of dollars to market their drugs to prescribers and patients and meticulously tracked their return on that investment. In one recent survey published by the AMA, even though nine in ten general practitioners reported prescription drug abuse to be a moderate to large problem in their communities, 88% of the respondents said they were confident in their prescribing skills, and nearly half were comfortable using opioids for chronic non-cancer pain.[80] These results are directly due to Manufacturer Defendants' fraudulent marketing campaign.

173. Manufacturer Defendants:

a. misrepresented the truth about how opioids lead to addiction;

b. misrepresented that opioids improve function;

c. misrepresented that addiction risk can be managed;

d. misled doctors, patients, and payors through misleading terms like "pseudoaddiction;

e. falsely claimed that opioid withdrawal is simply managed;

f. misrepresented that increased doses pose no significant additional risks;

g. falsely omitted or minimized the adverse effects of opioids and overstated the risks of alternative forms of pain treatment.

174. Underlying each of Manufacturer Defendants' misrepresentations and deceptions in promoting the long-term continuous use of opioids to treat chronic pain was Manufacturer

[80] Hwang, Catherine S. et al., "Prescription Drug Abuse A National Survey of Primary Care Physicians.," *JAMA Intern Med.* 2015;175(2):302–304.

Defendants' collective effort to hide from the medical community the fact that there exist no adequate and well-controlled studies of opioid use longer than 12 weeks.[81]

A. Manufacturer Defendants Misrepresented How Opioids Lead To Addiction.

175. Manufacturer Defendants' fraudulent representation that opioids are rarely addictive is central to Manufacturer Defendants' scheme. Through their well-funded, comprehensive, aggressive marketing efforts, Manufacturer Defendants succeeded in changing the perceptions of many physicians, patients, and health care payors and in getting them to accept that addiction rates are low and that addiction is unlikely to develop when opioids are prescribed for pain. That, in turn, directly led to the expected, intended, and foreseeable result that doctors prescribed more opioids to more patients – thereby enriching Manufacturer Defendants.

176. For example, Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining opioids from multiple sources, or theft.

177. For another example, Endo sponsored a website, painknowledge.com, through APF, which claimed that: "[p]eople who take opioids as prescribed usually do not become addicted." Although the term "usually" is not defined, the overall presentation suggests that the rate is so low as to be immaterial. The language also implies that as long as a prescription is given, opioid use will not become problematic. The website also contained a flyer called "Pain: Opioid Therapy." This publication included a list of adverse effects that omitted significant adverse effects including hyperalgesia, immune and hormone dysfunction, cognitive impairment,

[81] Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. *Physicians for Responsible Opioid Prescribing*, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).

tolerance, dependence, addiction, and death. The website also claimed in 2009 that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life and "improved function" as benefits of opioid therapy.

178. For another example, Endo distributed a patient education pamphlet edited by Dr. Portenoy entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*. It claimed that "[a]ddicts take opioids for other reasons [than pain relief], such as unbearable emotional problems." This implies that patients prescribed opioids for genuine pain will not become addicted, which is unsupported and untrue.

179. For another example, Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009) in conjunction with the AAPM, ACPA and APF, which described as a "myth" the fact that opioids are addictive and asserts as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain."

180. The guide states as a "fact" that "Many studies" show that opioids are rarely addictive when used for chronic pain. No such studies exist.

181. For another example, Purdue sponsored and Janssen provided grants to APF to distribute *Exit Wounds* (2009) to veterans, which taught, "[l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications"

182. For another example, Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which inaccurately claimed that less than 1% of

children prescribed opioids would become addicted.[82] This publication also falsely asserted that pain is undertreated due to "misconceptions about opioid addiction."

183. For another example, in the 1990s, Purdue amplified the pro-opioid message with promotional videos and featuring Dr. Portenoy and other doctors, which claimed, "the likelihood that the treatment of pain using an opioid drug which is prescribed by a doctor will lead to addiction is extremely low."[83]

184. Rather than honestly disclose the risk of addiction, Manufacturer Defendants attempted to portray those who were concerned about addiction as callously denying treatment to suffering patients. To increase pressure on doctors to prescribe chronic opioid therapy, Manufacturer Defendants turned the tables: they suggested that doctors who failed to treat their patients' chronic pains with opioids were failing their patients and risking professional discipline, while doctors who relieved their patients' pain using long-term opioid therapy were following the compassionate (and professionally less risky) approach. Manufacturer Defendants claimed that purportedly overblown worries about addiction cause pain to be under- treated and opioids to be over-regulated and under-prescribed. The Treatment Options guide funded by Purdue and Cephalon states "[d]espite the great benefits of opioids, they are often underused." The APF publication funded by Purdue, *A Policymaker's Guide to Understanding Pain & Its Management*, laments that: "Unfortunately, too many Americans are not getting the pain care

[82] In support of this contention, it misleadingly cites a 1996 article by Dr. Kathleen Foley concerning cancer pain.

[83] Excerpts from one such video, including the statement quoted here, may be viewed at "Thousands Die Annually from Pain Med Overdose," *The Wall Street Journal*, 14 Dec. 2012, http://www.wsj.com/video/thousands-die-annually-from-pain-med-overdose/6E7C0A5F-48F5-47CE-9A0E-64439EF7A5AB.html.

they need and deserve. Some common reasons for difficulty in obtaining adequate care include . . . misconceptions about opioid addiction."[84]

185. *Let's Talk Pain*, sponsored by APF, AAPM and Janssen, likewise warns, "strict regulatory control has made many physicians reluctant to prescribe opioids. The unfortunate casualty in all of this is the patient, who is often undertreated and forced to suffer in silence." The program says, "[b]ecause of the potential for abusive and/or addictive behavior, many health care professionals have been reluctant to prescribe opioids for their patients…. This prescribing environment is one of many barriers that may contribute to the undertreatment of pain, a serious problem in the United States."

186. The Joint Commission even published a guide sponsored by Purdue on pain management that stated "[s]ome clinicians have inaccurate and exaggerated concerns about addiction, tolerance and risk of death. This attitude prevails despite the fact there is no evidence that addiction is a significant issue when persons are given opioids for pain control."[85]

B. Manufacturer Defendants Misrepresent That Opioids Improve Function.

187. Manufacturer Defendants produced, sponsored, or controlled materials with the expectation that, by instructing patients and prescribers that opioids would improve patient functioning and quality of life, patients would demand opioids and doctors would prescribe them. These claims also encouraged doctors to continue opioid therapy for patients in the belief that lack of improvement in quality of life could be alleviated by increasing doses or prescribing supplemental short-acting opioids to take as-needed for breakthrough pain.

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[84] This claim also appeared in a 2009 publication by APF, *A Reporter's Guide*.

[85] Hirsch, Ronald, "The Opioid Epidemic: It's Time to Place Blame Where It Belongs," *Observer.com*, 23 May 2016. Web. 25 Oct. 2017.

188. Research such as a 2008 study in the journal *Spine* has shown that pain sufferers prescribed opioids long-term suffered addiction that made them more likely to be disabled and unable to work.[86] Despite this lack of evidence of improved function, and the existence of evidence to the contrary, Manufacturer Defendants consistently promoted opioids as capable of improving patients' function and quality of life without disclosing the lack of evidence for this claim.

189. Claims that opioids improve patients' function are misleading because such claims have "not been demonstrated by substantial evidence or substantial clinical experience."[87]

190. The Federation of State Medical Boards' Responsible Opioid Prescribing (2007), sponsored by drug companies including Cephalon, Endo and Purdue, taught that relief of pain itself improved patients' function: "While significant pain worsens function, relieving pain should reverse that effect and improve function."

191. The APF's *Treatment Options: A Guide for People Living with Pain* taught patients that opioids, when used properly "give [pain patients] a quality of life we deserve." The Treatment Options guide notes that non-steroidal anti-inflammatory drugs (e.g., Aspirin or Ibuprofen) have greater risks with prolonged duration of use, but there was no similar warning for opioids. The APF distributed 17,200 copies of this guide in one year alone, according to its 2007 annual report, and it is available online.

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[86] Dersh, Jeffrey et al., "Prescription Opioid Dependence is Associated with Poorer Outcomes in Disabling Spinal Disorders," Spine (Phila Pa 1976). 2008 Sep 15;33(20):2219-27.

[87] Letter from Thomas W. Abrams, RPh., MBA, Dir., Div. of Marketing, Advertising and Communications to Brian A. Markison, Chairman, King Pharmaceuticals, Re: NDA 21-260 (March 24, 2008).

192. Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* with the AAPM, ACPA and APF. This guide features a man playing golf on the cover and lists examples of expected functional improvement from opioids like sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs.

193. The guide states as a "fact" that "opioids may make it *easier* for people to live normally" (emphasis in the original). The myth/fact structure implies authoritative support for the claim that does not exist. Targeting older adults also ignored heightened opioid risks in this population.

194. The website *Let's Talk Pain* in 2009 featured a video interview, which was edited by Janssen personnel, claiming that opioids were what allowed a patient to "continue to function," falsely implying that her experience would be representative.

195. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which inaccurately claimed that "multiple clinical studies" have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients," with the implication these studies presented claims of long-term improvement.

196. To the contrary, the sole reference for the functional improvement claim (i) noted the absence of long- term studies and (ii) stated, "For functional outcomes, the other analgesics were significantly more effective than were opioids."

C. Manufacturer Defendants Misrepresent That Addiction Risk Can Be Effectively Managed.

197. Manufacturer Defendants each continue to maintain to this day that most patients safely can take opioids long-term for chronic pain without becoming addicted. Presumably to explain why doctors encounter so many patients addicted to opioids, Manufacturer Defendants

admit that some patients could become addicted, but that doctors can avoid or manage that risk by using screening tools or questionnaires. These tools, they say, identify those with higher addiction risks (stemming from personal or family histories of substance abuse, mental illness, or abuse) so doctors can more closely monitor patients at greater risk of addiction.

198. There are three fundamental flaws in Manufacturer Defendants' representations that doctors can consistently identify and manage the risk of addiction. First, there is no reliable scientific evidence that doctors can depend on the screening tools currently available to materially limit the risk of addiction. Even if the tools are effective, they may not always be applied correctly, and are subject to manipulation by patients. Second, there is no reliable scientific evidence that high-risk or addicted patients identified through screening can take opioids long-term without triggering or worsening addiction, even with enhanced monitoring. Third, there is no reliable scientific evidence that patients not identified through such screening can take opioids long-term without significant danger of addiction.

199. Addiction is difficult to predict on a patient-by-patient basis, and there are no reliable, validated tools to do so. An Evidence Report by the Agency for Healthcare Research and Quality ("AHRQ"), which "systematically review[ed] the current evidence on long-term opioid therapy for chronic pain" identified "[n]o study" that had "evaluated the effectiveness of risk mitigation strategies, such as use of risk assessment instruments, opioid management plans, patient education, urine drug screening, prescription drug monitoring program data, monitoring instruments, more frequent monitoring intervals, pill counts, or abuse-deterrent formulations on

outcomes related to overdose, addiction, abuse or misuse."[88] Furthermore, attempts to treat high-risk patients, like those who have a documented predisposition to substance abuse, by resorting to patient contracts, more frequent refills, or urine drug screening are not proven to work in the real world, but doctors were misled to employ them.[89]

200. Manufacturer Defendants' misrepresentations regarding the risk of addiction from chronic opioid therapy were particularly dangerous because they were aimed at general practitioners or family doctors, who treat many chronic conditions but lack the time and expertise to closely manage patients on opioids by reviewing urine screens, counting pills, or conducting detailed interviews to identify other signs or risks of addiction. One study conducted by pharmacy benefits manager Express Scripts concluded, after analyzing 2011–2012 narcotic prescription data of the type regularly used by Manufacturer Defendants to market their drugs, that, of the more than half million prescribers of opioids during that time period, only 385 were identified as pain specialists.[90]

201. In materials they produced, sponsored, or controlled, Manufacturer Defendants instructed patients and prescribers that screening tools can identify patients predisposed to addiction, thus making doctors feel more comfortable prescribing opioids to their patients and

[88] "The Effectiveness and Risks of Long-Term Opioid Treatment of Chronic Pain," *Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services,* Evidence Report/Technology Assessment No. 218, ES-2, ES-21, Sep. 2014.

[89] *See* Von Korff, Michael et al., "Long-Term Opioid Therapy Reconsidered," Ann Intern Med. 2011 Sep 6; 155(5): 325–328; Manchikanti, L. et al., "American Society of Interventional Pain Physicians (ASIPP) Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain: Part 1, Evidence Assessment," 15 Pain Physician (Special Issue) S1-S66; Part 2 – Guidance, 15 Pain Physician (Special Issue) S67-S116 (2012).

[90] "Identifying High Prescribers," *Lab.express-scripts.com*, Express Scripts, 9 Jun 2014. Web. 25 Oct. 2017.

patients more comfortable starting on opioid therapy for chronic pain. Manufacturer Defendants' marketing scheme contemplated a "heads we win; tails we win" outcome: patients deemed low risk were to receive opioids on a long-term basis without enhanced monitoring, while and patients deemed high risk were also to receive opioids on a long-term basis but with more frequent visits, tests and monitoring.

202. APF's *Treatment Options: A Guide for People Living with Pain* falsely reassured patients that "opioid agreements" between doctors and patients can "ensure that you take the opioid as prescribed."

203. Endo paid for a 2007 supplement available for continuing education credit in the Journal of Family Practice written by a doctor who became a member of Endo's speaker's bureau in 2010. This publication, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*, (i) recommended screening patients using tools like (a) the *Opioid Risk Tool* created by Dr. Webster and linked to Janssen or (b) the *Screener and Opioid Assessment for Patients with Pain*, and (ii) taught that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.

204. Purdue sponsored a 2011 webinar taught by Dr. Webster, entitled *Managing Patient's Opioid Use: Balancing the Need and Risk*. This publication misleadingly taught prescribers that screening tools, urine tests, and patient agreements have the effect of preventing "overuse of prescriptions" and "overdose deaths."

D. Manufacturer Defendants Mislead With Use Of Purportedly Scientific Terms Like "Pseudoaddiction."

205. Manufacturer Defendants instructed patients and prescribers that signs of addiction are actually the product of untreated pain, thereby causing doctors to prescribe ever more opioids despite signs that the patient was addicted. The word "pseudoaddiction" was

concocted by Dr. J. David Haddox, who later went to work for Purdue, and was popularized in opioid therapy for chronic pain by Dr. Portenoy, who consulted for Manufacturer Defendants Cephalon, Endo, Janssen, and Purdue. Much of the same language appears in other Manufacturer Defendants' treatment of this issue, highlighting the contrast between "undertreated pain" and "true addiction"—as if patients could not experience both.

206. In the materials they produced, sponsored, or controlled, Manufacturer Defendants misrepresented that the concept of "pseudoaddiction" is substantiated by scientific evidence.

207. FSMB's *Responsible Opioid Prescribing* taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, which are in fact signs of genuine addiction, are all really signs of "pseudoaddiction."

208. Purdue did not mention that the author who concocted both the word and the phenomenon it purported to describe became a Purdue Vice President; nor did Purdue disclose the lack of scientific evidence to support the existence of "pseudoaddiction."[91]

209. Purdue posted an unbranded pamphlet entitled *Clinical Issues in Opioid Prescribing* on its unbranded website, PartnersAgainstPain.com, in 2005, and circulated this pamphlet after 2007. The pamphlet listed conduct including "illicit drug use and deception" that it claimed was not evidence of true addiction but was indicative of "pseudoaddiction" caused by untreated pain. It also stated, "Pseudoaddiction is a term which has been used to describe patient behaviors that may occur when pain is untreated … . Even such behaviors as illicit drug use and

[91] Weissman, DE & Haddox, JD, "Opioid Pseudoaddiction – an Iatrogenic Syndrome," Pain. 1989 Mar;36(3):363-6.

deception can occur in the patient's efforts to obtain relief. Pseudoaddiction can be distinguished from true addiction in that the behaviors resolve when the pain is effectively treated."

E. Manufacturer Defendants Claim Withdrawal Is Easily Managed.

210. To underplay the risk and impact of addiction, Manufacturer Defendants claimed that, while patients become physically "dependent" on opioids, physical dependence is not the same as addiction and can be addressed, if and when pain relief is no longer desired, by gradually tapering patients' dosage to avoid the adverse effects of withdrawal. Manufacturer Defendants fail to disclose the difficult and painful effects that patients can experience when removed from opioids – an adverse effect that also makes it less likely that patients can stop using the drugs.

211. In materials Manufacturer Defendants produced, sponsored, and controlled, Manufacturer Defendants made misrepresentations to persuade doctors and patients that withdrawal from their opioids was not a problem and they should not be hesitant about prescribing or using opioids. These claims were not supported by scientific evidence.

212. A CME sponsored by Endo entitled *Persistent Pain in the Older Adult*, taught that withdrawal symptoms can be avoided entirely by tapering a patient's opioid dose by 10% to 20% per day for ten days. This claim was misleading because withdrawal in a patient already physically dependent would take longer than ten days – when it succeeds at all.[92]

213. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that "Symptoms of physical dependence can often be ameliorated by

[92] *See* Ballantyne, Jane C. et al., "New Addiction Criteria: Diagnostic Challenges Persist in Treating Pain With Opioids," *Intl. Assoc. for the Study of Pain*, Vol. XXI No. 5, Dec. 2013.

gradually decreasing the dose of medication during discontinuation," but the guide did not disclose the significant hardships that often accompany cessation of use.

F. Manufacturer Defendants Misrepresent Increased Doses Pose No Significant Additional Risks.

214. Manufacturer Defendants claimed that patients and prescribers could increase doses of opioids indefinitely without added risk, even when pain was not decreasing or when doses had reached levels that were "frighteningly high," suggesting that patients would eventually reach a stable, effective dose. Each of Manufacturer Defendants' claims was deceptive in that it omitted warnings of increased adverse effects that occur at higher doses.

215. In materials Manufacturer Defendants produced, sponsored or controlled, Manufacturer Defendants instructed patients and prescribers that patients could remain on the same dose indefinitely, assuaging doctors' concerns about starting patients on opioids or increasing their doses during treatment, or about discontinuing their patients' treatment as doses escalated. These claims were not supported by scientific evidence.

216. APF's *Treatment Options: A Guide for People Living with Pain* claims that some patients "need" a larger dose of an opioid, regardless of the dose currently prescribed. The guide taught that opioids differ from NSAIDs because they have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. The publication attributes 10,000 to 20,000 deaths annually to NSAID overdose when the true figure was closer to 3,200 at the time.[93]

217. Cephalon sponsored a CME written by KOL Dr. Webster, *Optimizing Opioid Treatment for Breakthrough Pain*, offered by Medscape, LLC from September 28, 2007 through

[93] Tarone, Robert E. et al., "Nonselective Nonaspirin Nonsteroidal Anti-Inflammatory Drugs and Gastrointestinal Bleeding: Relative and Absolute Risk Estimates from Recent Epidemiologic Studies," Am J Ther. 2004 Jan-Feb;11(1):17-25.

December 15, 2008. The CME taught that non-opioid analgesics and combination opioids containing non-opioids such as aspirin and acetaminophen are less effective at treating breakthrough pain because of dose limitations on the non-opioid component.

218. Endo claimed in 2009 that opioids may be increased until "you are on the right dose of medication for your pain," at which point further dose increases would not be required.

219. Endo distributed a patient education pamphlet edited by KOL Dr. Portenoy entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*, which was published on Endo's website. In Q&A format, it asked, "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased. … You won't 'run out' of pain relief."

220. APF's *A Policymaker's Guide to Understanding Pain & Its Management* taught that dose escalations are "sometimes necessary," even indefinite ones, but did not disclose the risks from high-dose opioids. This publication is still available online.

221. Purdue sponsored *Overview of Management Options*, a CME issued by the AMA in 2003, 2007, 2010, and 2013. The 2013 version remains available for CME credit. The CME was edited by KOL Dr. Portenoy, among others, and taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses.

G. Manufacturer Defendants Deceptively Omit or Minimize The Effects Of Opioids And Overstate Risks Of Alternative Forms Of Pain Treatment.

222. In materials they produced, sponsored or controlled, Manufacturer Defendants omitted known risks of chronic opioid therapy and emphasized or exaggerated risks of competing products so that prescribers and patients would be more likely to choose opioids and would favor opioids over other therapies such as over-the-counter acetaminophen or over-the-counter or prescription NSAIDs. None of these claims was supported by scientific evidence.

223. In addition to failing to disclose in promotional materials the risks of addiction, abuse, overdose, and respiratory depression, Manufacturer Defendants routinely ignored the risks of hyperalgesia, a "known serious risk associated with chronic opioid analgesic therapy in which the patient becomes more sensitive to certain painful stimuli over time;"[94] hormonal dysfunction;[95] decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly;[96] neonatal abstinence syndrome (when an infant exposed to opioids prenatally suffers withdrawal after birth), and potentially fatal interactions with alcohol or benzodiazepines, which are used to treat post-traumatic stress disorder and anxiety. Post-traumatic stress disorder and anxiety also often accompany chronic pain symptoms.[97]

224. APF's *Exit Wounds* omits warnings of the risk of potentially fatal interactions between opioids and certain anti-anxiety medicines called benzodiazepines, commonly prescribed to veterans with post-traumatic stress disorder.

225. Because of Manufacturer Defendants' campaign of deception, promoting opioids over safer and more effective drugs, opioid prescriptions increased even as the percentage of patients visiting a doctor for pain remained constant. A study of 7.8 million doctor visits between

[94] Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. *Physicians for Responsible Opioid Prescribing*, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).

[95] *See* Daniell, H.W., "Hypogonadism in Men Consuming Sustained-Action Oral Opioids, J Pain. 2002 Oct;3(5):377-84.

[96] *See* Bernhard M., "The Risk of Fall Injury in Relation to Commonly Prescribed Medications Among Older People – a Swedish Case-Control Study," *European Journal of Public Health*, Volume 25, Issue 3, 1 June 2015, Pages 527–532.

[97] Seal, Karen H., "Association of Mental Health Disorders With Prescription Opioids and High-Risk Opioids in US Veterans of Iraq and Afghanistan," 307(9) J. Am. Med. Ass'n 940-47 (2012).

2000 and 2010 found that opioid prescriptions increased from 11.3% to 19.6% of visits, as NSAID and acetaminophen prescriptions fell from 38% to 29%, driven primarily by the decline in NSAID prescribing.[98]

VII. Manufacturer Defendants Deceptively Promote Their Drugs.

226. While Manufacturer Defendants worked in concert to expand the market for opioids, they also worked to maximize their individual shares of that market. Each Defendant promoted opioids for chronic pain through sales representatives (which Manufacturer Defendants called "detailers" to deemphasize their primary sales role) and small group speaker programs to contact individual prescribers nationwide and in Marshall County. By establishing close relationships with doctors, Manufacturer Defendants could disseminate their misrepresentations in targeted, one-on-one settings that allowed them to differentiate their opioids and to allay individual prescribers' concerns about prescribing opioids for chronic pain.

227. Manufacturer Defendants' detailers pitched opioids to general practitioners to treat common conditions such as back aches and knee pain. Sales detailers showered prescribers with gifts, invited doctors to dinner seminars, and flew them to weekend junkets at resort hotels, where they were encouraged to prescribe opioids and promote it to colleagues back home.[99]

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[98] Daubresse, M. et al., "Ambulatory Diagnosis and Treatment of Nonmalignant Pain in the United States," 2000-2010, 51(10) Med. Care 870-78 (2013). For back pain alone, the percentage of patients prescribed opioids increased from 19% to 29% between 1999 and 2010, even as the use of NSAIDs or acetaminophen declined from 39.9% to 24.5% of these visits; and referrals to physical therapy remained steady. *See also* Mafi, JN et al., "Worsening Trends in the Management and Treatment of Back Pain," JAMA Intern Med. 2013 Sep 23;173(17):1573-81.

[99] Ryan, Harriet, et al., "'You want a Description of Hell?' Oxycontin's 12-Hour Problem," *The Los Angeles Times*, 5 May 2016. Web. 25 Oct. 2017.

Purdue, for example, used presentations and training materials to train sales reps to remind doctors there is no ceiling on the amount of OxyContin a patient can be prescribed.[100]

228. Manufacturer Defendants compensated sales detailers for this conduct:

- A West Virginia supervisor for Purdue told one of his highest performing sales detailers in a 1999 letter she could "blow the lid off" her sales and earn a trip to Hawaii if she persuaded more doctors to write larger doses.

- In an August 1996 memo headlined "$$$$$$$$$$$$ It's Bonus Time in the Neighborhood!" a Purdue manager reminded Tennessee detailers that raising dosage strength was the key to a big payday.[101]

229. Manufacturer Defendants developed sophisticated methods for selecting doctors for sales visits based on the doctors' prescribing habits. Under common industry practice, Manufacturer Defendants purchase and closely analyze prescription sales data from IMS Health, a healthcare data collection, management and analytics corporation. This data allows them to track precisely the rates of initial and renewal prescribing by individual doctors, which allows them to target and tailor their sales practices. Sales representatives visited hundreds of thousands of doctors and disseminated the misinformation and materials described above throughout the United States, including doctors in Marshall County.

230. The IMS Heath data was vital to Manufacturer Defendants' sales departments. Sales detailers working on commission could identify doctors writing a small number of opioid prescriptions who might be persuaded to write more. Manufacturer Defendants also could identify physicians writing large numbers of prescriptions.

231. The highest prescribing doctors were added to Purdue's confidential roster of physicians suspected of recklessly prescribing. Purdue calls that list Region Zero and has been

[100] *Id.*

[101] *Id.*

adding names to it since 2002. An LA Times investigation only recently discovered the existence of that list. As of 2013, Purdue acknowledged there were over 1,800 doctors in Region Zero. Purdue had reported less than 8% on the list to authorities.[102]

232. Manufacturer Defendants also offer discounts, known as "chargebacks," based on sales to certain downstream customers. Distributor Defendants provide information on the downstream customer purchases to Manufacturer Defendants to obtain the chargeback.[103]

233. Manufacturer Defendants also collected information about the highest prescribing doctors. For example, "Purdue collected extensive evidence suggesting illegal trafficking of OxyContin and, in many cases, did not share it with law enforcement or cut off the flow of pills. A former Purdue executive, who monitored pharmacies for criminal activity, acknowledged that even when the company had evidence pharmacies were colluding with drug dealers, it did not stop supplying distributors selling to those stores."[104] Instead, sales detailers would continue to visit these places trafficking its opioids.

VIII. Manufacturer Defendants Knew Their Marketing Was False, Unfounded, Dangerous, and Would Harm Plaintiff.

234. Manufacturer Defendants made, promoted, and profited from their misrepresentations—individually and collectively—knowing that their statements regarding the risks, benefits, and superiority of opioids for chronic pain were false and misleading. Cephalon

[102] Girion, Lisa, "Dissecting an OxyContin Pipeline," *Portland Press Herald*, 16 July 2016. Web. 25 Oct. 2017.

[103] Press Release, "Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations," *U.S. Dept. of Justice*, 11 July 2017. Web. 16 Sept. 2017.

[104] Girion, Lisa, "Dissecting an OxyContin Pipeline," *Portland Press Herald*, 16 July 2016. Web. 25 Oct. 2017.

and Purdue entered into settlements in the hundreds of millions of dollars to resolve criminal and federal charges involving nearly identical conduct.

235. Manufacturer Defendants expected and intended that their misrepresentations would induce doctors to prescribe, patients to use, and payors to pay for their opioids for chronic pain.

236. When they began their deceptive marketing practices, Manufacturer Defendants recklessly disregarded the harm that their practices were likely to cause. As their scheme was implemented, and as the reasonably foreseeable harm began to occur, Manufacturer Defendants knew that it was occurring. Manufacturer Defendants closely monitored their own sales and the habits of prescribing doctors, which allowed them to see sales balloon—overall, in individual practices, and for specific indications. Their sales representatives knew what types of doctors were receiving their messages and how they were responding. Moreover, Manufacturer Defendants had access to, and carefully monitored government and other data that tracked the explosive rise in opioid use, addiction, injury, and death.

IX. Manufacturer Defendants Fraudulently Concealed Their Misrepresentations.

237. Manufacturer Defendants tried to avoid detection of, and to fraudulently conceal, their deceptive marketing and conspiratorial behavior.

238. Manufacturer Defendants disguised their own roles in the deceptive marketing by funding and working through Front Groups purporting to be patient advocacy and professional organizations and through paid KOLs. Manufacturer Defendants purposefully hid behind the assumed credibility of the front organizations and KOLs and relied on them to vouch for the accuracy and integrity of Manufacturer Defendants' false and misleading statements about opioid use for chronic pain.

239. Manufacturer Defendants did not disclose their role in shaping, editing, and approving the content of the Front Groups publications. Manufacturer Defendants secretly influenced these purportedly "educational" or "scientific" materials in emails, correspondence, and meetings with KOLs, Front Groups, and public relations companies.

240. Besides hiding their own role in generating the deceptive content, Manufacturer Defendants manipulated their promotional materials and the scientific literature to make it appear these items were accurate, truthful, and supported by substantial scientific evidence. Manufacturer Defendants distorted the meaning or import of materials they cited and offered them as evidence for propositions the materials did no support. The true lack of support for Manufacturer Defendants' deceptive messages was not apparent to the medical professionals who relied upon them in making treatment decisions. The false and misleading nature of Manufacturer Defendants' marketing was not known to, nor could it reasonably have been discovered by, Plaintiff or its residents.

241. Manufacturer Defendants also concealed their participation by extensively using the public relations companies they hired to work with Front Groups to produce and disseminate deceptive materials.

242. Manufacturer Defendants concealed from the medical community, patients, and health care payors facts sufficient to arouse suspicion of the existence of claims that Plaintiff now asserts. Plaintiff did not discover the existence and scope of Manufacturer Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

243. Through the public statements, marketing, and advertising, Manufacturer Defendants' deceptions deprived Plaintiff of actual or implied knowledge of facts sufficient to put it on notice of potential claims.

X. Distributor Defendants Have A Duty to Report and Stop Suspicious Orders of Opioids.

A. Distributor Defendants' Duties.

244. Distributor Defendants have an affirmative duty to act as a gatekeeper guarding against the diversion of the highly addictive, dangerous opioid drugs.

245. Congress created a closed system of distribution of prescription opioids with the Controlled Substance Act of 1970 that required all manufacturers and distributors to obtain registrations and investigate, report, and stop suspicious orders of prescription opioids.

246. The closed loop system established by the Controlled Substances Act combats diversion by requiring that "all legitimate handlers of controlled substances must obtain a DEA [Drug Enforcement Administration] registration and, as a condition of maintaining such registration, must take reasonable steps to ensure that their registration is not being utilized as a source of diversion."[105]

247. The Controlled Substances Act and its implementing regulations restrict the distribution of controlled substances by requiring drug distributors and manufacturers to monitor, identify, stop, and report suspicious orders of controlled substances, including orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.[106]

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[105] Letter from Joseph T. Rannazzisi, Deputy Assis. Admin., Office of Diversion Control, to Cardinal Health, Sept. 27, 2006, p. 1 ("2006 Rannazzisi Letter") (filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW, Doc. 14-51 (D.D.C.).)

[106] *See* 21 U.S.C. §§ 801-971; 21 C.F.R. §§ 1300-1321.

248. The Distributor Defendants are required to register with the Drug Enforcement Administration (DEA), pursuant to the Controlled Substances Act.[107]

249. Accordingly, each of the Defendant Distributors is a "registrant" as a wholesale distributor in the chain of distribution of Schedule II controlled substances (opioids) with a duty to comply with all security requirements imposed under that statutory scheme.

250. In evaluating a distributor's operations, the DEA considers "(1) whether the distributor has maintained "effective control[s] against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels"; (2) whether the distributor has complied with applicable state and local laws; (3) whether the distributor has previously been convicted under federal or state laws for a crime related to the sale of controlled substances; (4) the distributor's past experience with controlled substances; and (5) "such other factors as may be relevant to and consistent with the public health and safety."[108]

251. Distributors are "one of the key components of the distribution chain" and "must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as Congress has expressly declared that the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people."[109]

252. Federal regulations require that Distributor Defendants "shall provide effective controls and procedures to guard against theft and diversion of controlled substances."[110]

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[107] *See* 21 U.S.C. § 823(b), (e); 28 C.F.R. § 0.100; *Masters Pharm., Inc.*, 861 F.3d at 21.

[108] *Masters Pharm., Inc.*, 861 F.3d at 212 (quoting 21 U.S.C. § 823(b), (e)).

[109] 2006 Rannazzisi letter, p. 1.

[110] 21 C.F.R. § 1301.71(a). *See also* 21 U.S.C. § 823(b).

253. Distributor Defendants must not ship a suspicious order.[111] Every registrant under the Controlled Substances Act, including Distributor Defendants, is required to notify the DEA of suspicious orders and stop such orders, thereby ensuring that prescription opioids are not diverted for illegal purposes.

254. The implementing federal regulations provide, "[t]he registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant.[112]

255. "Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."[113] The criteria for suspicious orders:

> are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported a suspicious. Likewise, a registrant need not wait for a "normal pattern" to develop over time before determining whether a particular order is suspicious. The size of the order alone, whether or not it deviates from a normal pattern, is enough to trigger the registrant's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant's customer base and the patterns throughout the relevant segment of the regulated industry.[114]

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[111] *See* Prevoznik, Thomas W., "Distributor Initiative: A National Perspective," *Deadiversion.usdoj.gov*, U.S. Dept. of Justice, Drug Enforcement Administration, 22 Oct. 2013. Web. 25 Oct. 2017.

[112] 21 C.F.R. § 1301.74(b) (emphasis added).

[113] 21 C.F.R. § 1301.74(b).

[114] Letter from Joseph T. Rannazzisi, Deputy Assis. Admin., Office of Diversion Control, to Cardinal Health, Dec. 27, 2007, p. 1 ("2007 Rannazzisi Letter") (filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW, Doc. 14-8 (D.D.C.).)

256. "Once a distributor has reported a suspicious order, it must make one of two choices: decline to ship the order, or conduct some "due diligence" and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order."[115]

257. Indiana also places duties on drug distributors. Indiana law requires that "[e]very person who manufactures or distributes any controlled substance within this state or who proposes to engage in the manufacture or distribution of any controlled substance within this state, must obtain biennially a registration issued by the board [Indiana state board of pharmacy] in accordance with the board's rules."[116]

258. The Indiana Administrative Code also requires that "[e]very person who manufactures, distributes, or dispenses any controlled substance or who proposes to engage in the manufacture, distribution, or dispensing of any controlled substance shall obtain annually a registration unless exempted by law. . . ."[117]

259. Indiana law provides that the state board of pharmacy "shall register an applicant to manufacture or distribute controlled substances unless it determines that the issuance of that registration would be inconsistent with the public interest."[118] One of the factors the Indiana state board of pharmacy shall consider in determining the public interest is "maintenance of effective

[115] *Masters Pharm., Inc.*, 861 F.3d at 212–13.

[116] Ind. Code § 35-48-3-3(a). *See also* Ind. Code § 35-48-1-6 (""Board" refers to the Indiana state board of pharmacy.")

[117] 856 Ind. Admin. Code 2-3-2.

[118] Ind. Code § 35-48-3-4(a).

controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels. . . ."[119]

260. The Indiana Administrative Code further requires distributors to inform the board of pharmacy of suspicious orders when discovered by the distributor. A distributor:

> shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Indiana Board of Pharmacy of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.[120]

261. The Distributor Defendants knew they were required to monitor, detect, and halt suspicious orders. Industry compliance guidelines established by the Healthcare Distribution Management Association, the trade association of pharmaceutical distributors, explain that distributors are "[a]t the center of a sophisticated supply chain" and therefore "are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers." [121] The guidelines set forth recommended steps in the "due diligence" process, and note in particular "[i]f an order meets or exceeds a distributor's threshold, as defined in the distributor's monitoring system, or is otherwise characterized by the distributor as an order of interest, the distributor should not ship to the customer, in fulfillment of

[119] Ind. Code § 35-48-3-4(a)(1).

[120] 856 Ind. Admin. Code 2-3-33(b) (emphasis added). *See also* Ind. Code § 35-48-3-7 ("Persons registered to manufacture, distribute, or dispense controlled substances under this article shall keep records and maintain inventories in conformance with the record-keeping and inventory requirements of federal law and with any additional rules the board issues.").

[121] Healthcare Distribution Management Association (HDMA) Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances (filed in *Cardinal Health, Inc. v. Holder*, No. 12-5061, Doc. No. 1362415 (App'x B) (D.C. Cir. Mar. 7, 2012).

that order, any units of the specific drug code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest."[122]

262. The Distributor Defendants sold prescription opioids in Marshall County, which Defendants knew were likely to be diverted in Marshall County.

263. Each Distributor Defendant owes a duty to monitor and detect suspicious orders of prescription opioids.

264. Each Distributor Defendant owes a duty to investigate and refuse suspicious orders of prescription opioids.

265. Each Distributor Defendant owes a duty to report suspicious orders of prescription opioids.

266. Each Distributor Defendant owes a duty to prevent the diversion of prescription opioids into illicit markets in Indiana and Marshall County.

267. The foreseeable harm resulting from a breach of these duties is the diversion of prescription opioids for nonmedical purposes and the subsequent opioid addiction crisis ravaging Marshall County and the damages caused thereby.

B. The ARCOS Database.

268. Pills made and distributed in the United States are tracked in a confidential DEA database called Automation of Reports and Consolidated Orders System (ARCOS).

269. The ARCOS database "is an automated, comprehensive drug reporting system which monitors the flow of DEA controlled substances from their point of manufacture through

[122] *Id.*

commercial distribution channels to point of sale or distribution at the dispensing/retail level—hospitals, retail pharmacies, practitioners, mid-level practitioners, and teaching institutions."[123]

270. Distributor Defendants are required to maintain records of their transactions involving controlled substances and are required to file reports of distributions of certain controlled substances to the ARCOS database.[124]

271. ARCOS registrants must report all movement of drugs quarterly but they may elect to report on a monthly basis. There are approximately 30,000,000+ transactions reported yearly.[125] ARCOS data is used in criminal and civil prosecutions and provides data for trend analysis for other agencies.

272. Neither the DEA nor the Defendants will voluntarily disclose the ARCOS data.

273. However, ARCOS data for West Virginia revealed that distributors and manufacturers knew of, but did not report or stop, suspicious orders of prescription opioids.

XI. Distributor Defendants Breached Their Duties And The DEA Gets Involved.

A. The DEA Sent Letters to the Distributor Defendants.

274. As a result of the Distributor Defendants' failure to comply with federal law, the DEA has taken a number of actions against them.

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[123] "Automation of Reports and Consolidated Orders System (ARCOS)," *Deadiversion.usdoj.gov,* U.S. Dept. of Justice, Drug Enforcement Administration. Web. 23 Sept. 2017.

[124] *See* 2006 Rannazzisi letter, p. 2. *See also* "Automation of Reports and Consolidated Orders System (ARCOS), Questions & Answers," Deadiversion.usdoj.gov. Web. 25 Oct. 2017.

[125] "Automation of Reports and Consolidated Orders System (ARCOS), Questions & Answers," *Deadiversion.usdoj.gov*, U.S. Dept. of Justice, Drug Enforcement Administration. Web. 25 Oct. 2017.

275. On September 27, 2006, the DEA sent a letter to "every commercial entity in the United States registered with the Drug Enforcement Administration (DEA) to distribute controlled substances."[126]

276. The letter states that manufacturers and distributors "share responsibility for maintaining appropriate safeguards against diversion" and "given the extent of prescription drug abuse in the United States, along with the dangerous and potentially lethal consequences of such abuse, **even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm**."[127]

277. The letter advised that "DEA will use its authority to revoke and suspend registrations in appropriate cases."[128]

278. The letter also provides that "in addition to reporting all suspicious orders, a distributor has a statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels."[129]

279. The letter further discusses that "distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as Congress has expressly declared that the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people."[130]

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[126] 2006 Rannazzisi Letter, p. 1.

[127] *Id*., p. 2 (emphasis added).

[128] *Id*.

[129] *Id*.

[130] *Id*., p.1.

280. The DEA sent another letter on December 27, 2007 to "reiterate the responsibilities of controlled substance manufacturers and distributors to inform DEA of suspicious orders."[131]

281. This letter reminded manufacturers and distributors of their obligation to "maintain effective controls against diversion" and "design and operate a system to disclose to the registrant suspicious orders of controlled substances."[132]

282. The letter stated that in terms of reporting suspicious orders:

> Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributor. Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviates from the normal pattern of what pharmacies generally order.
>
> When reporting an order as suspicious, registrants must be clear in their communications with DEA that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by a registrant indicating "excessive purchases" do not comply with the requirement to report suspicious orders, even if the registrant calls such reports "suspicious order reports."[133]

283. The 2007 letter also said that "[f]ailure to maintain effective controls against diversion is inconsistent with the public interest . . . and may result in the revocation of the registrant's DEA Certificate of Registration."[134]

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[131] 2007 Rannazzisi Letter, p. 1.

[132] *Id.*

[133] *Id.*, at p. 2.

[134] *Id.*, at pp. 1-2.

284. The 2007 letter also references the final order issued in *Southwood Pharmaceuticals, Inc.*, 72 FR 36487 (2007), which "[i]n addition to discussing the obligation to report suspicious orders when discovered" and "some criteria to use when determining whether an order is suspicious", the order "also specifically discusses your obligation to maintain effective controls against the diversion of controlled substances."[135]

B. DEA Actions against the Distributor Defendants.

285. Because of the Distributor Defendants' refusal to comply with their legal obligations, the DEA has repeatedly taken administrative action to force compliance. The United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Division, reported that the DEA issued final decisions in 178 registrant actions between 2008 and 2012.[136] "The Office of Administrative Law Judges issued a recommended decision in a total of 117 registrant actions before the DEA issued its final decision, including 76 actions involving orders to show cause and 41 actions involving immediate suspension orders."[137]

286. In 2007, the DEA suspended AmerisourceBergen's license to distribute from an Orlando facility, alleging that the distribution center "had inadequate controls against diversion of controlled substances by retail internet pharmacies."[138]

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[135] *Id*., at p. 2.

[136] "The Drug Enforcement Administration's Adjudication of Registrant Actions," *Oig.justice.gov*, United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, I-2014-003, p. 6 (May 2014). Web. 25 Oct. 2017.

[137] *Id.*

[138] Reuters Staff, "Amerisource says US DEA OKs Controlled Drug Permit," *Reuters*, 27 Aug. 2007. Web. 16, Sept. 2017.

287. In 2012, AmerisourceBergen received subpoenas from United States' prosecutors and the DEA requesting "documents concerning a program for controlling and monitoring diversion of controlled substances into channels other than for legitimate medical, scientific, and industrial purposes."[139]

288. In 2008, McKesson agreed to pay more than $13 million to settle DEA claims that it failed to report hundreds of suspicious orders from internet pharmacies that sold drugs online to customers who did not have legal prescriptions. [140]

289. As DEA Acting Administrator Michele M. Leonhart publicly stated in 2008, "[b]y failing to report suspicious orders for controlled substances that it received from rogue Internet pharmacies, the McKesson Corporation fueled the explosive prescription drug abuse problem we have in this country."[141]

290. In 2008, McKesson entered into a Settlement Agreement with the DOJ and an Administrative Memorandum of Agreement with the DEA requiring that McKesson "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 CFR § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program."[142]

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[139] Reuters Staff, "US Seeks Info on Drug Diversion from Amerisource Bergen," *Reuters*, 9 Aug. 2012. Web. 2, Oct. 2017.

[140] *See* Press Release, "McKesson Corporation Agrees to Pay More than $13 Million to Settle Claims that it Failed to Report Suspicious Sales of Prescription Medications," *U.S. Dept. of Justice*, 2 May 2008. Web. 2 Oct. 2017.

[141] *Id.*

[142] 2017 McKesson Administrative Memorandum of Agreement, p. 3, *Justice.gov*, U.S. Dept. of Justice. Web. 25 Oct. 2017.

291. As a result of these agreements, "McKesson recognized that it had a duty to monitor its sales of all controlled substances and report suspicious orders to DEA."[143]

292. Despite these prior penalties, McKesson's pattern of failing to report suspicious orders continued for many years.

293. From 2008 until 2013, McKesson "supplied various U.S. pharmacies an increasing amount of oxycodone and hydrocodone pills, frequently misused products that are part of the current opioid epidemic."[144] "[E]ven after designing a compliance program after the 2008 settlement, McKesson did not fully implement or adhere to its own program."[145]

294. In January 2017, the DOJ announced that McKesson had agreed to pay a record $150 million fine and suspend the sale of controlled substances from distribution centers in Colorado, Ohio, Michigan, and Florida.[146]

295. In an Administrative Memorandum of Agreement entered into between McKesson, DOJ, and the DEA in 2017, the DOJ and DEA recognized, for example:

- "McKesson failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations at McKesson Distribution Centers. . . ;"[147]

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[143] *Id*.

[144] Press Release, "McKesson Agrees to Pay Record $150 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs," *U.S. Dept. of Justice Office of Public Affairs*, 17 Jan. 2017. Web. 9 Oct. 2017.

[145] *Id.*

[146] *Id.*

[147] 2017 McKesson Administrative Memorandum of Agreement, p. 3, *Justice.gov*, U.S. Dept. of Justice. Web. 25 Oct. 2017.

- "McKesson failed to properly monitor its sales of controlled substances and/or report suspicious order to the DEA, in accordance with McKesson's obligations under the 2008 Agreements, the CSA, and 21 C.F.R. § 1301.74(b);"[148]

- "McKesson failed to conduct adequate due diligence of its customers, failed to keep complete and accurate records in the CMSP files maintained for many of its customers, and bypassed suspicious order reporting procedures set forth in the McKesson CMSP;"[149]

- "McKesson failed to inform the DEA Field Offices and/or DEA Headquarters of suspicious orders of controlled substances made by its customers . . . including orders of unusual size, orders deviating substantially from normal patterns, and orders of unusual frequency, as required by and in violation of 21 C.F.R. §1301.74(b), 21 U.S.C. § 842(a)(5), and the 2008 Agreements;"[150]

- "McKesson failed to report suspicious orders for controlled substances in accordance with the standards identified and outlined in the DEA Letters;"[151]

- "The McKesson Distribution Centers distributed controlled substances to pharmacies even though those Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the course of their professional practice, as required by 21 C.F.R. § 1306.04(a)."[152]

296. McKesson acknowledged in the 2017 settlement that "at various times during the Covered Time Period, it did not identify or report to DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance

[148] *Id*,. at p. 4.

[149] *Id.*

[150] *Id.*

[151] *Id.*

[152] *Id.*

contained in the DEA Letters about the requirements set forth in 21 C.F.R. §1301.74(b) and 21 U.S.C. § 842(a)(5)."[153]

297. McKesson also acknowledged in the 2017 settlement that "at various times during the Covered Time Period, [McKesson] did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious in a manner fully consistent with the requirements set forth in the 2008 MOA."[154]

298. In 2008, Cardinal Health agreed to pay $34 million to settle claims that it failed to report suspicious sales of abused controlled substances.[155] As stated in the DOJ's 2008 Press Release, "Cardinal's conduct allowed the "diversion" of millions of dosage units of hydrocodone from legitimate to non-legitimate channels. "**DEA regulations require all manufacturers and distributors to report suspicious orders of controlled substances and, more specifically, to 'design and operate a system to disclose to the registrant suspicious orders of controlled substances**.' Registrants are required to inform DEA of suspicious orders upon discovery."[156]

299. DEA Acting Administrator Michele M. Leonhart stated at the time:

> Despite DEA's repeated attempts to educate Cardinal Health on diversion awareness and prevention, Cardinal engaged in a pattern of failing to report blatantly suspicious orders for controlled substances filled by its distribution facilities located throughout the United States," . . . "Cardinal's negligent conduct contributed to our nation's serious pharmaceutical abuse problem. This substantial civil penalty underscores DEA's determination to prevent pharmaceutical diversion and protect the public health and safety by continuing to hold

[153] *Id.*, at p. 5.

[154] *Id.*

[155] Press Release, "Cardinal Health Inc., Agrees to Pay $34 Million to Settle Claims that it failed to Report Suspicious Sales of Widely-Abused Controlled Substances," *The Colorado U.S. Attorney's Office*, 2 Oct. 2008. Web. 2 Oct. 2017.

[156] *Id.* (emphasis original).

companies responsible if they fail to fulfill their obligations under the Controlled Substance Act."[157]

300. Cardinal Health entered into an Administrative Memorandum of Agreement ("2008 MOA") with the DEA as well. The 2008 MOA required Cardinal Health "to maintain a compliance program designed to detect and prevent diversion of controlled substances as required under the Controlled Substances Act and applicable DEA regulations."[158]

301. In 2012, Cardinal Health reached a settlement with the DEA to resolve allegations that a Florida distribution center "failed to maintain effective controls against the diversion of controlled substances, specifically oxycodone."[159]

302. Cardinal Health entered in an Administrative Memorandum of Agreement with the DOJ and DEA (the "2012 MOA"), which noted that "[o]n February 2, 2012, the DEA, by its Administrator, Michele M. Leonhart, issued an Order to Show Cause and Immediate Suspension of Registration to Cardinal Lakeland."[160] The Order to Show Cause alleged:

a. "Despite the 2008 MOA, Cardinal Lakeland failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels as evidenced by sales to certain customers of Cardinal;

b. Cardinal Lakeland failed to report suspicious orders of controlled substances as required by 21 C.F.R. § 1301.74(b); and

c. Cardinal Lakeland failed to conduct meaningful due diligence of its retail pharmacies, including its retail chain pharmacy customers to ensure that

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[157] *Id.*

[158] Press Release, "DEA Suspends for Two Years Pharmaceutical Wholesale Distributor's Ability to Sell Controlled Substances from Lakeland, Florida Facility," *Drug Enforcement Administration*, 15 May 2012. Web. 16 Sept. 2017.

[159] *Id.*

[160] 2012 Cardinal Health Administrative Memorandum of Agreement, p. 1.

> controlled substances were not diverted into other than legitimate channels."[161]

303. In the 2012 MOA, Cardinal Health agreed "to maintain a compliance program designed to detect and prevent diversion of controlled substances as required under the CSA and applicable DEA regulations" and Cardinal Health "shall inform DEA of suspicious orders as required by 21 C.F.R. § 1301.74(b)."[162]

304. In 2016, Cardinal Health agreed to pay $44 million in fines to resolve allegations "that it violated the Controlled Substances Act (CSA) in Maryland, Florida and New York by failing to report suspicious orders of controlled substances to pharmacies located in those states."[163]

C. Distributor Defendants Misled the Public Concerning their Duties and Compliance.

305. In *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration* (D.C. Cir), the Healthcare Distribution Management Association (HDMA), a trade association run by the Distributor Defendants, and National Association of Chain Drug Stores (NACDS) submitted briefs regarding the legal duty of wholesale distributors.[164] Inaccurately denying the legal duties that Distributor Defendants have failed to fulfill, they argued that**:**

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[161] *Id.*

[162] *Id.* at 3–4.

[163] Press Release, "Cardinal Health Agrees to $44 Million Settlement for Alleged Violations of Controlled Substances Act," *U.S. Dept. of Justice, The U.S. Attorney's Office, District of Maryland*, 23 Dec. 2016. Web. 23 Sept. 2017.

[164] The Healthcare Distribution Management Association (HDMA)—now known as the Healthcare Distribution Alliance (HDA)—is a national, not-for-profit trade association that represents the nation's primary, full-service healthcare distributors whose membership includes, among others: AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation. *See generally* HDA, About, *https://www.healthcaredistribution.org/about*. Web. 6

- The Associations complained that the "DEA has required distributors not only to report suspicious orders, but to *investigate* orders (e.g., by interrogating pharmacies and physicians) and take action to *halt* suspicious orders before they are filled."[165]

- The Associations argued that, "DEA now appears to have changed its position to require that distributors not only *report* suspicious orders, but *investigate* and *halt* suspicious orders. 80 Fed. Reg. at 55,421, 55,475-77, 55,479. Such a change in agency position must be accompanied by an acknowledgement of the change and a reasoned explanation for it. In other words, an agency must "display awareness that it is changing position" and "show that that there are good reasons for the new policy." *Fox Television Stations, Inc.*, 556 U.S. at 515. This is especially important here, because imposing intrusive obligations on distributors threatens to disrupt patient access to needed prescription medications."[166]

- The Associations alleged "Section 1301.71 by its terms restricts DEA's authority to delineate the requirements for "effective controls"—stating that, in evaluating a control system, the Administrator "shall use the security requirements set forth in §§ 1301.72-1301.76." 21 C.F.R. § 1301.71(a) (emphasis added). Nothing in Sections 1301.72-1301.76 requires distributors to investigate the legitimacy of orders, or to halt shipment of any orders deemed to be suspicious."[167]

- The Associations complained that the purported "practical infeasibility of requiring distributors to investigate and halt suspicious orders (as well as report them) underscores the importance of ensuring that DEA has complied with the APA before attempting to impose such duties."[168]

Oct. 2017. The National Association of Chain Drug Stores (NACDS) is a national, not-for-profit trade association that represents traditional drug stores and supermarkets and mass merchants with pharmacies whose membership includes, among others: Walgreen Company, CVS Health, Rite Aid Corporation and Walmart. *See generally* NACDS, Mission, *https://www.nacds.org/about/mission/*. Web. 6 Oct. 2017.

[165] Brief for HDMA and NACDS filed in *Masters Pharm., Inc. v. Drug Enf't Admin.*, USCA Case #15-1335, Doc. No. 1607110, pp. 4–5 (D.C. Cir. Apr. 4, 2016).

[166] *Id.*, at p. 8.

[167] *Id.*, at p.14.

[168] *Id.*, at p. 22.

- The Associations alleged (inaccurately) that "DEA's regulations had sensibly imposed a duty on distributors simply to *report* suspicious orders, but left it to DEA and its agents to investigate and halt suspicious orders."[169]

- Also inaccurately, the Associations argued that, "[i]mposing a duty on distributors—which lack the patient information and the necessary medical expertise—to investigate and halt orders may force distributors to take a shot-in-the-dark approach to complying with DEA's demands."[170]

306. Rejecting the Associations' contentions, the United States Court of Appeals for the District of Columbia issued an opinion stating that "[o]nce a distributor has reported a suspicious order, it must make one of two choices: decline to ship the order, or conduct some "due diligence" and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order (the Shipping Requirement)."[171]

307. The Distributor Defendants have also undertaken to fraudulently convince the public that they were complying with their legal obligations, including those imposed by licensing regulations. Through such statements, the Distributor Defendants attempted to assure the public they were working to curb the opioid epidemic.

308. For example, a Cardinal Health executive said the company "deploys 'advanced analytics, technology, and teams of anti-diversion specialists and investigators who are embedded in our supply chain. This ensures that we are as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity.'"[172]

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[169] *Id.*, at p. 24–25.

[170] *Id.*, at p. 26.

[171] *Masters Pharm., Inc.*, 861 F.3d at 212–13.

[172] Bernstein, Lenny et al., "How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: 'No one was doing their job,'" *The Washington Post*, 22 Oct. 2016. Web. 6 Oct. 2017.

309. Given the sales volumes and the company's history of violations, this executive was either not telling the truth, or Cardinal Health had such a system, but it ignored the results.

310. Similarly, McKesson publicly stated that it has "put significant resources towards building a best-in-class controlled substance monitoring program to help identify suspicious orders and prevent prescription drug diversion in the supply chain," and "[o]ur team is deeply passionate about curbing the opioid epidemic in our country."[173]

311. Given McKesson's past conduct, this statement is either false, or the company ignored the results of its monitoring program.

312. Rather than abide by their duties, the Distributor Defendants and their association, the Healthcare Distribution Alliance, spent $13 million to lobby House and Senate members and their staff in favor of legislation called "Ensuring Patient Access and Effective Drug Enforcement Act" which, as one article described, "raises the standard for the diversion office to obtain an immediate suspension order. Now the DEA must show an "immediate" rather than an "imminent" threat to the public, a nearly impossible burden to meet against distributors, according to former DEA supervisors and other critics. They said the new law gives the industry something it has desperately sought: protection from having its drugs locked up with little notice."[174] After an explosive media report on the Distributor Defendants' lobbying effort, the

[173] Higham, Scott et al., "Drug Industry Hired Dozens of Officials from the DEA as the Agency tried to Curb Opioid Abuse," *The Washington Post*, 22 Dec. 2016. Web. 6 Oct. 2017.

[174] Bernstein, Lenny et al, "Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control," *The Washington Post*, 22 Oct. 2016. Web. 6 Oct. 2017.

Congressman who sponsored the bill and who was slated to be the President's new Drug Czar, withdrew his name from consideration.[175]

313. By misleading the public about the effectiveness of their controlled substance monitoring programs, the Distributor Defendants successfully concealed the facts giving rise to the claims that Marshall County now asserts.

314. In September 2017, 41 state Attorneys General served opioid manufacturers and distributors with subpoenas and document requests seeking information concerning how the companies marketed and distributed opioids.[176]

315. Meanwhile, the opioid epidemic ravages Marshall County because the fines and suspensions imposed by the DEA did not change the conduct of Distributor Defendants. The Distributor Defendants simply pay fines as a cost of doing business in their industry that generates billions of dollars in annual revenue. They hold multiple DEA registration numbers and when one facility is suspended, they simply ship from another facility.

316. The Distributor Defendants have abandoned their duties imposed under federal and state law, taken advantage of a lack of DEA law enforcement, and allowed diversion in Indiana and Marshall County for their economic benefit.

D. Distributor Defendants Breached their Duties.

317. "Because distributors handle such large volumes of controlled substances, and are the first major line of defense in the movement of legal pharmaceutical controlled substances . . .

[175] Chappell, Bill, "Tom Marino, Trump's Pick As Drug Czar, Withdraws After Damaging Opioid Report," *NPR.Org*, 17 Oct. 2017. Web. 25 Oct. 2017.

[176] Press Release, "A.G. Schneiderman, Bipartisan Coalition Of AGs Expand Multistate Investigation Into Opioid Crisis," *New York State Office of the Attorney General,* 19 Sept. 2017. Web. 6 Oct. 2017.

from legitimate channels into the illicit market, it is incumbent on distributors to maintain effective controls to prevent diversion of controlled substances. Should a distributor deviate from these checks and balances, the closed system created by the CSA collapses."[177]

318. The sheer volume of prescription opioids distributed to pharmacies in Marshall County and/or to pharmacies from which the Distributor Defendants knew the opioids were likely to be diverted into Marshall County, is excessive for the medical need of the community and facially suspicious. Some red flags are so obvious that no one who engages in the legitimate distribution of controlled substances can reasonably claim ignorance of them.

319. The Distributor Defendants failed to report suspicious orders originating from Marshall County or which the Distributor Defendants knew were likely to be diverted to Marshall County, to the federal and state authorities, including the DEA and the Indiana Board of Pharmacy.

320. The Distributor Defendants unlawfully filled suspicious orders of unusual size, orders deviating substantially from a normal pattern and/or orders of unusual frequency in Marshall County, and/or orders which Defendants knew or should have known were likely to be delivered and/or diverted into Marshall County.

321. The Distributor Defendants breached their duty to monitor, detect, investigate, refuse and report suspicious orders of prescription opioids originating from Marshall County, and/or in areas from which the Distributor Defendants knew opioids were likely to be diverted to Marshall County.

[177] Declaration of Joseph Rannazzisi, ¶ 10 (filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW, Doc. 14-2 (D.D.C. February 10, 2012).

322. The Distributor Defendants breached their duty to maintain effective controls against diversion of prescription opioids into other than legitimate medical, scientific, and industrial channels.

323. The Distributor Defendants breached their duty to design and operate a system to disclose suspicious orders of controlled substances and failed to inform state and federal authorities of suspicious orders when discovered, in violation of their duties under federal and state law.

324. The Distributor Defendants breached their duty to exercise due diligence to avoid filling suspicious orders that might be diverted into channels other than legitimate medical, scientific and industrial channels.

325. The unlawful conduct by the Distributor Defendants is purposeful and intentional. The Distributor Defendants violated the duties imposed by federal and state law.

326. The Distributor Defendants acted with actual malice in breaching their duties, i.e., they have acted with a conscious disregard for the rights and safety of other persons, and their actions had and continue to have a great probability of causing substantial harm.

327. The Distributor Defendants' repeated shipments of suspicious orders, over an extended period of time, in violation of public safety statutes, and without reporting the suspicious orders to the relevant authorities demonstrates wanton, willful, or reckless conduct or criminal indifference to civil obligations affecting the rights of others and justifies an award of punitive damages.

XII. The Manufacturer Defendants Also Fail to Prevent Diversion and Monitor, Report, and Stop Suspicious Orders.

328. The Manufacturer Defendants are under the same federal law duties as the Distributor Defendants to prevent diversion, and to monitor, report, and prevent suspicious orders of prescription opioids.

329. Like the Distributor Defendants, the Manufacturer Defendants were required to register with the DEA to manufacture schedule II controlled substances, like prescription opioids.[178] A requirement of such registration is the:

> maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes.[179]

330. Additionally, as registrants under Section 823, the Manufacturer Defendants were also required to monitor, report, and prevent suspicious orders of controlled substances:

> The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.[180]

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[178] *See* 21 U.S.C. § 823(a).

[179] 21 U.S.C. § 823(a)(1).

[180] 21 C.F.R. § 1301.74(b). *See also* 21 C.F.R. § 1301.02 ("Any term used in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter."); 21 C.F.R. § 1300.01 ("Registrant means any person who is registered pursuant to either section 303 or section 1008 of the Act (21 U.S.C. 823 or 958)."

331. Like the Distributor Defendants, the Manufacturer Defendants "must obtain biennially a registration issued by the board [Indiana state board of pharmacy] in accordance with the board's rules."[181]

332. Like the Distributor Defendants, the Manufacturer Defendants must "obtain annually a registration unless exempted by law"[182] and must "design and operate a system to disclose to the registrant suspicious orders of controlled substances. . . . [and] shall inform the Indiana Board of Pharmacy of suspicious orders when discovered by the registrant."[183]

333. The Manufacturer Defendants had access to and possession of the information necessary to monitor, report, and prevent suspicious orders and to prevent diversion. The Manufacturer Defendants paid "chargebacks" to the Distributor Defendants. A chargeback is a payment made by a manufacturer to a distributor after the distributor sells the manufacturer's product at a price below a specified rate. After a distributor sells a manufacturer's product to a pharmacy, for example, the distributor requests a chargeback from the manufacturer and, in exchange for the payment, the distributor identifies to the manufacturer the product, volume and the pharmacy to which it sold the product. Thus, the Manufacturer Defendants knew – just as the Distributor Defendants knew – the volume, frequency, and pattern of opioid orders being placed and filled. The Manufacturer Defendants built receipt of this information into the payment structure for the opioids provided to the Distributor Defendants.

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[181] Ind. Code § 35-48-3-3(a). *See also* Ind. Code § 35-48-1-6 (""Board" refers to the Indiana state board of pharmacy.")

[182] 856 Ind. Admin. Code 2-3-2.

[183] 856 Ind. Admin. Code 2-3-33(b) (emphasis added). *See also* Ind. Code § 35-48-3-7 ("Persons registered to manufacture, distribute, or dispense controlled substances under this article shall keep records and maintain inventories in conformance with the record-keeping and inventory requirements of federal law and with any additional rules the board issues.").

334. Federal statutes and regulations are clear: just like the Distributor Defendants, the Manufacturer Defendants are required to "design and operate a system to disclose . . . suspicious orders of controlled substances" and to maintain "effective controls against diversion."[184]

335. In 2017, the DOJ fined Defendant Mallinckrodt $35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements.[185] As described by the DOJ:

> The government alleged that Mallinckrodt failed to design and implement an effective system to detect and report "suspicious orders" for controlled substances – orders that are unusual in their frequency, size, or other patterns. From 2008 until 2011, the U.S. alleged, Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders. **Through its investigation, the government learned that manufacturers of pharmaceuticals offer discounts, known as "chargebacks," based on sales to certain downstream customers.** Distributors provide information on the downstream customer purchases to obtain the discount. The groundbreaking nature of the settlement involves requiring a manufacturer to utilize chargeback and similar data to monitor and report to DEA suspicious sales of its oxycodone at the next level in the supply chain, typically sales from distributors to independent and small chain pharmacy and pain clinic customers.[186]

336. The Memorandum of Agreement entered into by Mallinckrodt in 2017 confirms that "[a]s a registrant under the CSA, Mallinckrodt had a responsibility to maintain effective

[184] 21 C.F.R. § 1301.74; 21 U.S.C. § 823(a)(1).

[185] Press Release, "Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations," *U.S. Dept. of Justice*, 11 July 2017. Web. 16 Sept. 2017.

[186] *Id.* (emphasis added).

controls against diversion, including a requirement that it review and monitor these sales and report suspicious orders to DEA."[187]

337. The 2017 Memorandum of Agreement further details the DEA's allegations regarding Mallinckrodt's failures to fulfill its legal duties as an opioid manufacturer to prevent diversion:

> a. With respect to its distribution of oxycodone and hydrocodone products, Mallinckrodt's alleged failure to distribute these controlled substances in a manner authorized by its registration and Mallinckrodt's alleged failure to operate an effective suspicious order monitoring system and to report suspicious orders to the DEA when discovered as required by and in violation of 21 C.F.R. § 1301.74(b). The above includes, but is not limited to Mallinckrodt's alleged failure to:
>
> i. conduct adequate due diligence of its customers;
>
> ii. detect and report to the DEA orders of unusual size and frequency;
>
> iii. detect and report to the DEA orders deviating substantially from normal patterns including, but not limited to, those identified in letters from the DEA Deputy Assistant Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007:
>
> 1. orders that resulted in a disproportionate amount of a substance which is most often abused going to a particular geographic region where there was known diversion,
>
> 2. orders that purchased a disproportionate amount of a substance which is most often abused compared to other products, and
>
> 3. orders from downstream customers to distributors who were purchasing from multiple different distributors, of which Mallinckrodt was aware;
>
> iv. use "chargeback" information from its distributors to evaluate suspicious orders. Chargebacks include downstream purchasing information tied to certain discounts, providing Mallinckrodt with data on buying patterns for Mallinckrodt products; and

[187] Administrative Memorandum of Agreement between the United States Department of Justice, the Drug Enforcement Agency, and Mallinckrodt, plc. and its subsidiary Mallinckrodt, LLC, *Justice.gov*, U.S. Dept. of Justice, July 2017, p. 1. Web. 25 Oct. 2017.

> v. take sufficient action to prevent recurrence of diversion by downstream customers after receiving concrete information of diversion of Mallinckrodt product by those downstream customers.[188]

338. Defendant Mallinckrodt agreed that "certain aspects of Mallinckrodt's system to monitor and detect suspicious orders did not meet the standards outlined in letters from the DEA Deputy Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007."[189]

339. Defendant Mallinckrodt further agreed that:

> Mallinckrodt acknowledges and agrees that the obligations undertaken in this Program do not fulfill the totality of its obligations to maintain effective controls against the diversion of controlled substances or to detect and report to DEA suspicious orders for controlled substances. Mallinckrodt recognizes the importance of the prevention of diversion of the controlled substances they manufacture. Mallinckrodt will design and operate a system that meets the requirements of 21 CFR 1301.74(b). Mallinckrodt's suspicious order system will be designed to utilize all available transaction information to identify suspicious orders of any Mallinckrodt product. Further, Mallinckrodt agrees to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers.[190]

340. The 2017 Agreement also contained the following:

> Chargeback Data Monitoring. As part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers (distributors). The transaction information contains data relating to the direct customer sales of controlled substances to "downstream" registrants. Mallinckrodt receives this type of data only after it is submitted to Mallinckrodt by the direct customer, which is after the controlled substance has already been distributed. Mallinckrodt will report to the DEA when Mallinckrodt concludes that the chargeback data or other information indicates that a downstream registrant poses a risk of diversion.[191]

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[188] *Id*., at pp. 2-3.

[189] *Id*., at p. 4.

[190] *Id*.

[191] *Id*., at p. 5.

341. The same business practices utilized by Mallinckrodt regarding "charge backs" and receipt and review of data from opioid distributors regarding orders of opioids were utilized industry-wide among the Manufacturer and Distributor Defendants.

342. Through the charge back data, the Manufacturer Defendants could monitor suspicious orders of opioids.

343. The Manufacturer Defendants failed to monitor, report, and halt suspicious orders of opioids as required by federal law.

344. The Manufacturer Defendants' failures to monitor, report, and halt suspicious orders of opioids were intentional and unlawful.

345. The Manufacturer Defendants have misrepresented their compliance with federal law.

346. The wrongful actions and omissions of the Manufacturer Defendants have caused the diversion of opioids and have been a substantial contributing factor to and proximate cause of the opioid crisis ravaging Marshall County.

347. The Manufacturer Defendants' actions and omissions in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have enabled the unlawful diversion of opioids into Marshall County.

XIII. Defendants' Conduct and Breaches of Duties Caused the Plaintiff's Harm.

348. As the Manufacturer Defendants' efforts to expand the market for opioids increased so have the rates of prescription and sale of their products—and the rates of opioid related substance abuse, hospitalization, and death among the people of the State and Marshall County. The Distributor Defendants have continued to unlawfully ship these massive quantities of opioids into Marshall County, fueling the opioid epidemic.

349. There is "a parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes."[192]

350. "[O]pioid analgesics are widely diverted and improperly used, and the widespread use of the drugs has resulted in a national epidemic of opioid overdose deaths and addictions."[193]

351. The epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."[194]

352. The increased abuse of prescription painkillers along with growing sales has contributed to a large number of overdoses and deaths.[195]

353. The opioid epidemic has escalated in Marshall County with devastating effects. Substantial opioid-related substance abuse, hospitalization and death mirrors Defendants' increased distribution of opioids in this community.

354. Because of the well-established relationship between the use of prescription opioids and the use of non-prescription opioids, like heroin, the massive distribution of opioids to Marshall County and areas from which such opioids are being diverted into Marshall County has caused the Defendants-caused opioid epidemic to include heroin addiction, abuse, and death.

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[192] *See* Dart, Richard C. et al., "Trends in Opioid Analgesic Abuse and Mortality in the United States," New Engl. J. Med. 2015; 372:241-248 (Jan. 15, 2015).

[193] Volkow, Nora D. et al., "Opioid Abuse in Chronic Pain—Misconceptions and Mitigation Strategies," New Engl. J. Med. 2016; 374:1253-1263 (Mar. 31, 2016).

[194] *See* Califf, Robert M. et al., "A Proactive Response to Prescription Opioid Abuse," New Engl. J. Med. 2016; 374:1480-1485 (Apr. 14, 2016).

[195] *See* Press Release, "Prescription Painkiller Overdoses at Epidemic Levels," *U.S. Det. of Health and Human Services, Centers for Disease Control and Prevention,* 1 Nov. 2011. Web. 6 Oct. 2017.

355. Prescription opioid abuse, addiction, morbidity, and mortality are hazards to public health and safety in the State and in Marshall County.

356. Heroin abuse, addiction, morbidity, and mortality are hazards to public health and safety in the State and in Marshall County.

357. Defendants repeatedly and purposefully breached their duties under state and federal law, and such breaches are direct and proximate causes of, and/or substantial factors leading to, the widespread diversion of prescription opioids for nonmedical purposes into Marshall County.

358. The unlawful diversion of prescription opioids is a direct and proximate cause of, and/or substantial factor leading to, the opioid epidemic, prescription opioid abuse, addiction, morbidity and mortality in the State and Marshall County. This diversion and the epidemic are direct causes of foreseeable harms suffered by the Plaintiff. Defendants' intentional and unlawful conduct resulted in direct and foreseeable, past and continuing, economic damages to Plaintiff for which Plaintiff is entitled to means to abate the ongoing epidemic created by Defendants' wrongful and unlawful conduct.

359. Plaintiff's economic damages include reimbursement for the costs associated with past efforts to eliminate, control, and deal with the hazards to public health and safety.

360. Plaintiff's abatement damages include the costs to permanently eliminate the hazards to public health and safety and abate the ongoing public nuisance.

361. To eliminate the hazard to public health and safety, and abate the public nuisance, a "multifaceted, collaborative public health and law enforcement approach is urgently needed."[196]

362. "A comprehensive response to this crisis must focus on preventing new cases of opioid addiction, identifying early opioid-addicted individuals, and ensuring access to effective opioid addiction treatment while safely meeting the needs of patients experiencing pain."[197]

363. These community-based problems require community-based solutions that have been limited by "budgetary constraints at the state and Federal levels."[198]

364. Defendants' breach of their duties caused the skyrocketing in opioid addiction in Marshall County—an epidemic that threatens the safety and wellbeing of Marshall County and places added strain on the capacity of local public safety agencies and emergency medical departments. Having profited enormously through the aggressive sale, misleading promotion, and irresponsible distribution of opioids, Defendants are responsible for the financial burdens their conduct has inflicted upon the Plaintiff.

XIV. Defendants' Opioid Marketing and Diversion in Indiana.

365. Manufacturer Defendants have spent enormous amounts of money to infiltrate and influence the Marshall County market, including paying Indiana physicians for speaking engagements and other means of promoting their opioid drugs.[199]

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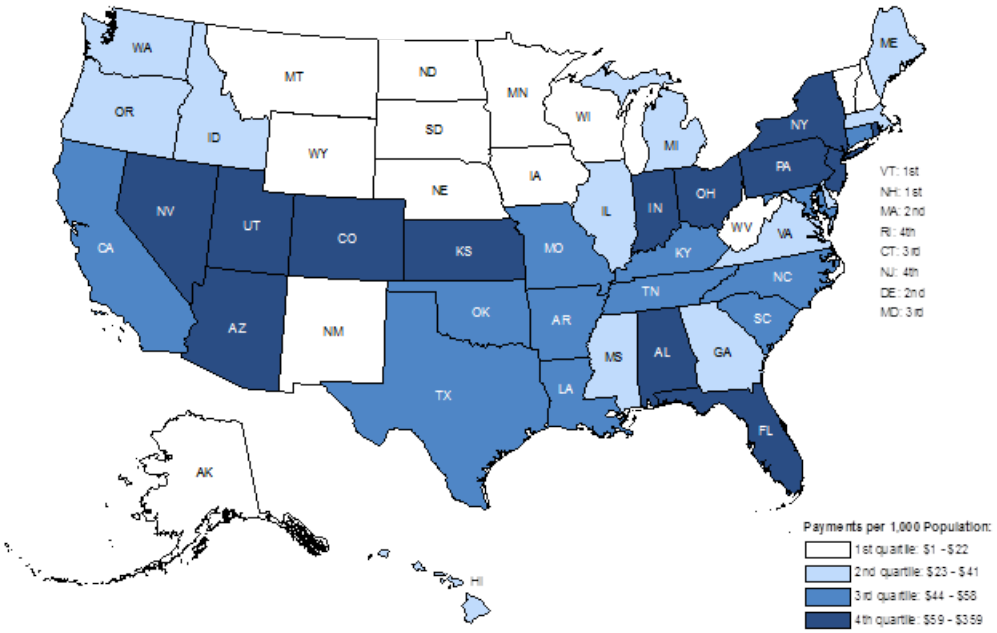
[196] *See* Rudd, Rose A. et al., "Increases in Drug and Opioid-Involved Overdose Deaths—United States, 2010–2015," MMWR Morb. Mortal Wkly. Rep. 2016 Dec 30; 65(5051):1445-1452.

[197] "The Prescription Opioid Epidemic: An Evidence-Based Approach," *Johns Hopkins Bloomberg School of Public Health*, p. 9 (Nov. 2015).

[198] *See* "Epidemic: Responding to America's Prescription Drug Abuse Crisis," *Executive Office of the President of the United States*, p. 1 (2011).

366. In a first-of-its-kind study, researchers at Boston Medical Center found that 1 in 12 doctors has received money from drug companies marketing prescription opioid medications.[200] The researchers found that from 2013 to 2015, doctors received more than $46 million in payments from drug companies pushing opioids. About two-thirds of the payments came from speaking fees.

367. Indiana recorded some of the most payments to doctors from drug companies pushing opioids:



[199] *See* "Dollars for Docs," *https://projects.propublica.org/docdollars/*, ProPublica. Web. 13 Oct. 2017.

[200] Hadland, S.E. et al., "Industry Payments to Physicians for Opioid Products, 2013-2015," 2017 Sep;107(9):1493-1495.

368. The Southern Indiana Drug Task Force reports that pharmaceutical company representatives began making frequent trips to Indiana in the late 1990s to promote new opioid painkillers – including Defendant Purdue's OxyContin.[201]

369. Sales of OxyContin rose 584% across the State of Indiana during the nine-year period between 1997 and 2005. Some areas of the state saw sales of OxyContin rise 1,234%.[202] During that same time period, statewide, hydrocodone sales grew 149%, from 287,238 grams sold in 1997 to 716,392 grams in 2005.[203]

370. When OxyContin was changed in late 2010 to purportedly be more difficult to snort or inject for a heroin-like high, Indiana law enforcement officials saw a rise in abuse of Defendant Endo's Opana.[204] Opana abuse is deadly because it is more potent, per milligram, than OxyContin. An Indiana State Police Sergeant reported that "This Opana pill has really kicked us in the rear" and that "[w]e've never seen an addiction like this."[205]

371. The FDA agreed and, shortly after pulled those products from the market.

372. The Manufacturer Defendants also purchased IMS Health data that informed the Manufacturers what the Distributors already knew from the data they provided to ARCOS and what the Manufacturers already knew from what they obtained in paying the Distributors chargebacks—that prescription opioids were flooding Indiana and Marshall County.

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[201] Castleman, Aaron, "DEA Data: OxyContin Sales Soared in Southern Indiana from '97 to '05, *WTHR.com*, 18 Aug. 2007, updated 15 Apr. 2016. Web. 25 Oct. 2017.

[202] *Id.*

[203] *Id.*

[204] Wisniewski, Mary, "Painkiller Opana, New Scourge of Rural America," *Reuters*, 27 Mar. 2012. Web. 25 Oct. 2017.

[205] *Id.*

373. Not surprisingly, several "pill mills" have been identified in Indiana.

374. Purdue and other Defendants were aware of specific "pill mills" and over-prescribers of their opioid drugs in Indiana and Marshall County, yet failed to report or halt suspicious orders to these entities, the foreseeable result of which was the diversion of opioids and the consequent damage to Plaintiff.

THE RESULTS OF DEFENDANTS' WRONGFUL CONDUCT ON INDIANA AND PLAINTIFF

I. Indiana and Marshall County are Flooded with Prescription Opioids as a Result of Defendants' Conduct.

375. In 2012, Indiana was one of the highest opioid prescribing states with an average of 112 opioid prescriptions for every 100 persons in the state. At that time, Marshall County had 100 opioid prescriptions for every 100 persons in the county and the rate peaked at 102 in 2013.[206]

376. IU Richard M. Fairbanks School of Public Health at Indiana University-Purdue University Indianapolis (IUPUI) discussing Indiana Scheduled Prescription Electronic Collection and Tracking Program (INSPECT) data noted, "[o]pioids represented a total of 4,708,068 dispensations in 2011. The number of opioids dispensed in Indiana increased by nearly 933,000 dispensations in 2012 for a total of 5,640,749 dispensations."[207]

[206] NextLevel Recovery Indiana. Web. 25 Oct. 2017. ("NextLevel Recovery Indiana").

[207] "The Indiana INSPECT Evaluation: Key Findings and Recommendations from a Descriptive Analysis of INSPECT Data," *IU Richard M. Fairbanks School of Public Health at Indiana University-Purdue University Indianapolis (IUPUI)*, Center for Health Policy (14-H58), Sept. 2014, p. 6 ("IUPUI INSPECT Evaluation Rpt.").

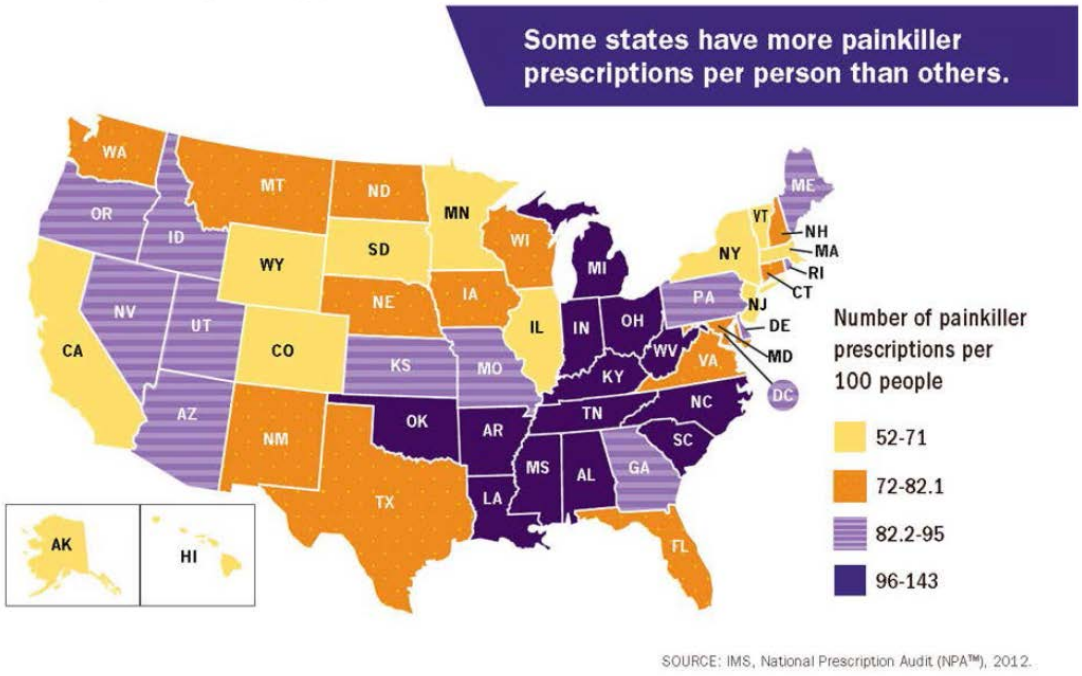
377. "In 2013, more than 10.5 million controlled substances (schedules II-V) were dispensed in Indiana and nearly half of them (5 million) were opioids."[208]

378. Indiana reported the 9th highest rate of opioid prescriptions per capita in the United States in 2012 and "**the fifth highest rate of diversion in the country. In 2013, the number of opioid prescriptions dispensed for Medicare beneficiaries was higher than the national average in 80% of Indiana counties, and the number of opioid prescriptions for Indiana Medicare beneficiaries exceeded the total county general population in 12 counties**. These figures are likely to be considerably higher when including opioid prescriptions paid for by private insurance and Medicaid."[209]

[208] *Id*., at p. 14.

[209] "Governor's Task Force on Drug Enforcement, Treatment & Prevention Final Report," *State of Indiana*, Fall 2016, p. 8 ("Gov.'s Task Force Rpt.").

Figure 1 Prescribing rates by state [3]



210

II. Opioids Are Killing Hoosiers.

A. Prescription Opioid Abuse and its Effect on Marshall County.

379. "Drug dependence is the most common adverse outcome associated with prescription drug use/misuse. Individuals can develop dependence on prescription opioids even when they take them as directed by their provider, due to the drug's ability to re-wire the brain."[211]

[210] "Report on the Toll of Opioid Use in Indiana and Marion County," *Indiana University Purdue University Indianapolis Richard M. Fairbanks School of Public Health*, Sept. 2016, p. 9 ("IU Rpt. on Opioid Use in Ind.") (citing IMS, National Prescription Audit (NPATM), 2012).

[211] IU Rpt. on Opioid Use in Ind., at p. 23.

380. A 2009 national survey found that of the 45 million chronic pain patients with mental illness, 8.9 million (or almost 20%) met criteria for substance abuse or dependency. "This national data reflects Indiana's experience."[212]

381. "In Indiana, 53% of people who are incarcerated are diagnosed with a substance use disorder. Of people who return to prison, 75% have a substance abuse disorder."[213]

382. "Drug abuse presents workplace safety and productivity issues. A first of its kind survey conducted by the National Safety Council and the Indiana Attorney General's office found that 80% of Indiana's employers have observed prescription drug misuse in their employees."[214]

383. "The cost of prescription opioid abuse nationally was estimated at $55.7 billion in 2007, with 46% of this amount attributable to workplace costs (e.g., lost productivity), 45% to healthcare costs (e.g., opioid abuse treatment), and 9% to costs in the criminal justice system."[215]

384. In her 2016 State of the Judiciary Address, Chief Justice Loretta Rush of the Indiana Supreme Court stated that, "This past year, my Supreme Court colleagues and I traveled the state to hear from our trial court judges from all 92 counties. They shared with us what became a recurring theme: the drug crisis . . . crippling their communities and flooding their courts."[216]

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[212] "First Do No Harm: The Indiana Healthcare Providers Guide to the Safe, Effective Management of Chronic Non-Terminal Pain," *Indiana Prescription Drug Abuse Task Force*, Version 1.0, p. 16 ("*First Do No Harm*").

[213] IU Rpt. on Opioid Use in Ind., at p. 7.

[214] *Id*.

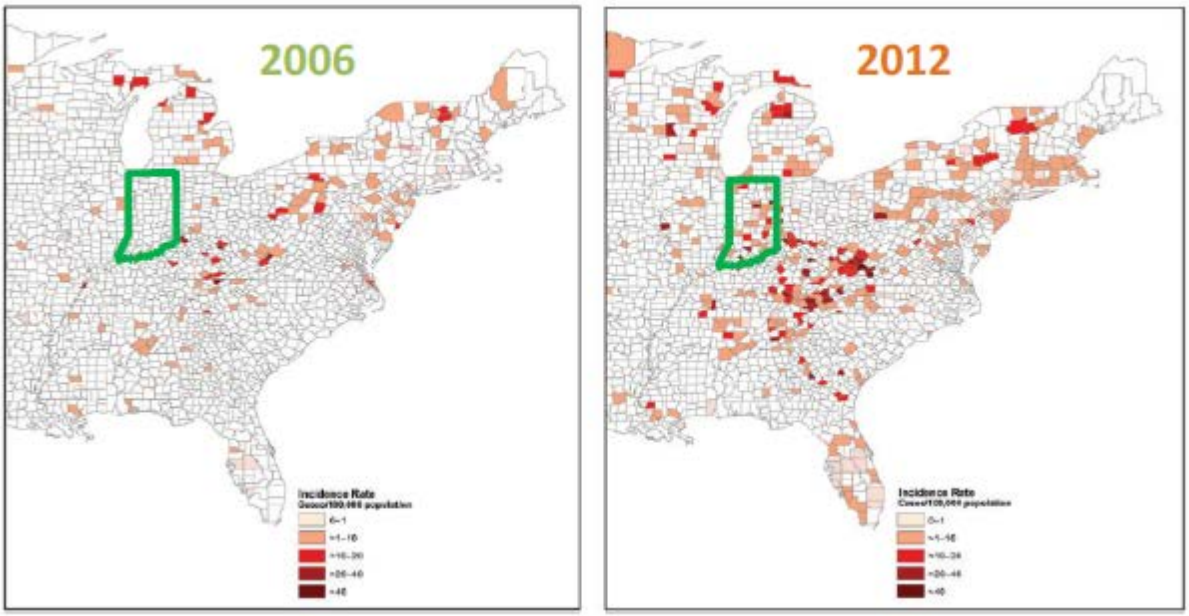
[215] *Id*., at p. 10.

[216] *Id*., at p. 45.

385. People who are addicted to prescription opioids are 40 times more likely to also be addicted to heroin.[217] "Indiana saw a more than 300 percent increase in the number of overdose deaths from heroin between 2010 and 2015, climbing from 54 to 239."[218]

386. "HIV and Hepatitis B and C are adverse health outcomes associated with injection drug use. Both are spread by the exchange of body fluids with an infected person, and are easily spread through needle sharing."[219] "Rates of acute hepatitis C virus infection among young suburban and rural persons who inject drugs have been increasing across much of the Midwest and Appalachia."[220]

Figure 26 Emerging epidemic of Hepatitis C virus infections among young non-urban persons who inject drugs in the United States, 2006–2012 [36]



[217] "Today's Heroin Epidemic," *Centers for Disease Control and Prevention*. Web. 25 Oct. 2017.

[218] Associated Press, "Indiana Posts Requests for Bids to Buy Thousands of Doses of Naloxone," *Fox59.com*, 29 May 2017. Web. 11 Oct. 2017.

[219] IU Rpt. on Opioid Use in Ind., at p. 33.

[220] *Id.*

387. "Trend data for 2000-2012 illustrates how reports of opioid abuse at treatment admission have substantially increased over time. U.S. trends for individuals seeking treatment for opioid dependence began to level off in 2012, but Indiana's did not."[221]

388. "People who use heroin are at risk for serious health consequences, such as drug dependence, spontaneous abortions, and chronic infection. If heroin is injected, the risks increase for HIV, hepatitis C, infections in the heart lining and valves, abscesses, liver disease, and pulmonary system problems. Heroin may contain other toxic substances that don't dissolve and may clog blood vessels leading to such vital organs as the brain, heart, liver, lungs or kidneys, causing patches of organ cells to die and negatively affecting their function. By far the most serious health consequence is death by overdose."[222]

389. "[R]ates of [heroin] dependence reported by people seeking treatment in Indiana have been on the rise, from 1.8% in 2001 to 7.9% in 2012."[223]

390. In 2013, Indiana's forensics labs saw 27 cases of seized fentanyl, an opioid that is much more potent and deadly than heroin. In 2016, it was more than 600 cases.[224]

B. Impact on Services Offered by Indiana and Marshall County.

391. It is estimated that Indiana's total health care costs from opioids in 2007 was $650 million, 12th highest among the states, and 8th among the states in per capita costs at $99.[225]

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[221] *Id*., at p. 23.

[222] *Id*., at p. 30.

[223] *Id*., at p. 30.

[224] Lapowsky, Issie, "Indiana, Reeling from Opioid Crisis, Arms Officials with Data," *Wired.com*, 14 Sept. 2017. Web. 10 Oct. 2017.

[225] IU Rpt. on Opioid Use in Ind., at p. 38.

392. The Indiana State Department of Health said "it saw a 60-percent increase in reports of non-fatal emergency room visits due to opioid overdoses from 2011-2015. At the same time, opioid-related deaths increased by an average of 3.5 percent each year."[226]

393. "There has been an increase in hospital Emergency Department (ED) visits resulting from abuse of opioids and heroin. In 2010 alone there were 641,940 visits to Indiana EDs due to non-fatal poisonings (90% of those poisonings were due to drug abuse). Not only do those visits have a dollar amount attached to them, but they also impact the ability of hospitals to deliver timely care."[227]

394. "The largest share of criminal justice costs ($5.1 billion) were attributable to incarceration ($2.3 billion or 44.1%). Police protection accounted for $1.5 billion (29.7%), legal/adjudication costs equaled $726 million (14.1%), and the remainder, $625 million (12.2%), resulted from property damage from crimes committed."[228]

395. "For Indiana, the estimated lifetime medical and work loss costs of drug overdose fatalities occurring in 2014 were $1.408 billion; costs incurred for non-fatal drug overdose emergency room visits were $31.9 million (2014). The lifetime medical and work loss costs of hospitalizations for all non-fatal poisonings over a four-year period (2007-2010) totaled $350 million. These estimates do not include costs of drug treatment and rehabilitation, costs to the criminal justice system, or other related costs."[229] The estimates also do not include "the

[226] Fisher, Jordan, "New Map Shows Scope of Indiana Opioid Epidemic," *Theindychannel.com*, RTV6, 15 May 2017. Web. 4 Oct. 2017.

[227] IU Rpt. on Opioid Use in Ind., at p. 6–7.

[228] *Id.*, at p. 37.

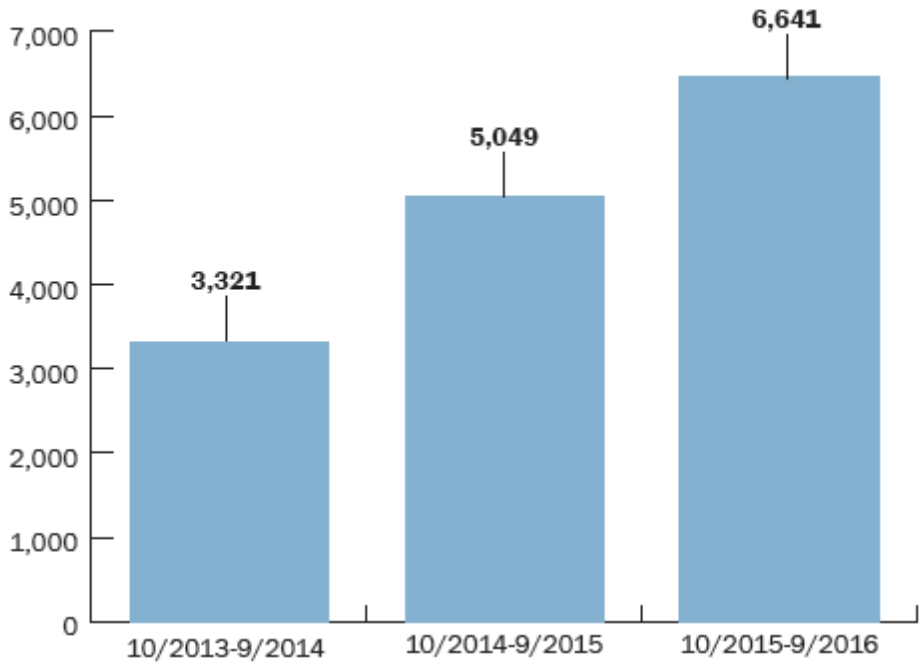
[229] *Id.*, at p. 38.

burgeoning costs of hospitalizing infants with Neonatal Abstinence Syndrome, or costs to the child welfare system."[230]

396. The costs are continuing to escalate because "[p]reliminary data for 2015 indicate a 75% increase in the reported number of individuals treated for drug overdose in [Indiana's] emergency departments, and 84 more reported overdose deaths than in 2014."[231]

397. "Between 2013 and 2016, there were total of 14,831 incidents where naloxone was administered by first responders in Indiana."[232]

FIGURE 6: Indiana First Responder Naloxone Incidents 2013-2016[494]



[230] *Id.*

[231] *Id.*

[232] Gov.'s Task Force Rpt., at p. 41.

398. Marshall County "experienced an increase in its rate of nonfatal emergency department visits due to opioid overdoses."[233]

399. In Marshall County, the average rate between 2011- 2015 for non-fatal emergency department visits due to opioid overdoses per 100,000 population was 28.1.[234] The rate peaked at 36.1 in 2012 and 2014.[235]

400. Data for Marshall County shows that the incidence rate per 100,000 of non-fatal emergency department visits due to opioid overdoses for 2016 and later is 133.2.[236]

401. For Marshall County, the incidence rate per 100,000 of non-fatal hospitalizations due to opioid overdoses in 2015 was 29.9.[237]

C. Impact on Children.

402. "[N]ational research indicates that 61% of infants and 41% of older children in out-of-home care are from families with some form of active SUD [(substance use disorder)]. These figures are increasing in Indiana where the percentage of children removed from homes

[233] Gallenberger, Michael, "County Opioid Profiles Released by State Health Officials," *Max983.net*, 16 May 2017. 27 Nov. 2017.

[234] "County Profiles of Opioid Use and Related Outcomes," *Indiana State Department of Health*. Web. 26 Oct. 2017.

[235] "County Profiles of Opioid Use and Related Outcomes," *Indiana State Department of Health*. Web. 26 Oct. 2017.

[236] "Non-Fatal Emergency Department Visits due to Opioid Overdoses (2016 and later)," *Stats Explorer, Epidemiology Resource Center, Indiana State Department of Health*. Web. 26 Oct. 2017.

[237] "Non-Fatal Hospitalizations due to Opioid Overdoses," *Stats Explorer, Epidemiology Resource Center, Indiana State Department of Health*. Web. 26 Oct. 2017.

due to parental SUD increased from 48% (5,101 children) in State Fiscal Year 2015, to 52.2% (6,223 children) in State Fiscal Year 2016."[238]

403. "Infants exposed to opioids in utero are often born with Neonatal Abstinence Syndrome (NAS), a condition that can result in increased irritability, hypertonia (spasticity), tremors, difficulty eating, vomiting, watery stools, seizures and respiratory distress."[239]

404. "In Indiana, NAS was diagnosed and reported in 657 infants born in 2014. The average length of hospital stay for these infants was 17.88 days, compared to infants without NAS, who stayed 2.24 days. The average hospital cost for an infant diagnosed with NAS was $97,555 compared to $4,167 for infants without NAS. The total hospital costs for 657 babies with NAS in Indiana was $64 million in 2014."[240]

D. Overdose Deaths.

405. "In 2016, more people died from drug overdoses in the U.S. than the total number of Americans killed in the Vietnam War. In Indiana, opioid overdose deaths rose 52 percent between 2015 and 2016 and have more than doubled in the last three years. Over the same period, . . . drug-related arrests by Indiana State Police increase[d] by more than 40 percent."[241]

[238] Gov.'s Task Force Rpt., at p. 17.

[239] IU Rpt. on Opioid Use in Ind., at p. 6.

[240] *Id*., at p. 43.

[241] Holcomb, Gov. Eric, "Gov. Eric Holcomb: Why I am focusing on the opioid crisis," *The Indianapolis Star*, 30 Sept. 2017. Web. 4 Oct. 2017.

406. Indiana is one of four states where the fatal drug overdose rate has more than quadrupled since 1999, with a total cost of drug overdoses in Indiana exceeding $1 billion a year in medical expenses and lost earnings.[242]

407. Like the United States, "Indiana loses more citizens to prescription opioid overdoses annually than to cocaine and heroin combined. The Centers for Disease Control and Prevention estimates that for every person who died due to opioid overdose in 2010, there were 15 abuse treatment admissions, 26 emergency department visits, 115 people who abuse or are dependent on opioids, and 733 non-medical opioid users."[243]

408. "In 2011, at least 718 Hoosiers died from unintentional drug poisoning, the majority of which involved opioids."[244]

409. Nearly six times as many Hoosiers died from drug overdose in 2014 as did in 2000 (twice the national rate), making Indiana residents more likely to die from a drug overdose than an automobile accident.[245]

410. As seen on the following chart, "nearly six times as many Hoosiers died from drug overdose in 2014 as did in 2000."[246]

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[242] Russell, John, "IU Announces $50M Plan to Tackle Growing Opioid Epidemic," *Indiana Business Journal*, 10 Oct. 2017. Web. 10 Oct. 2017.

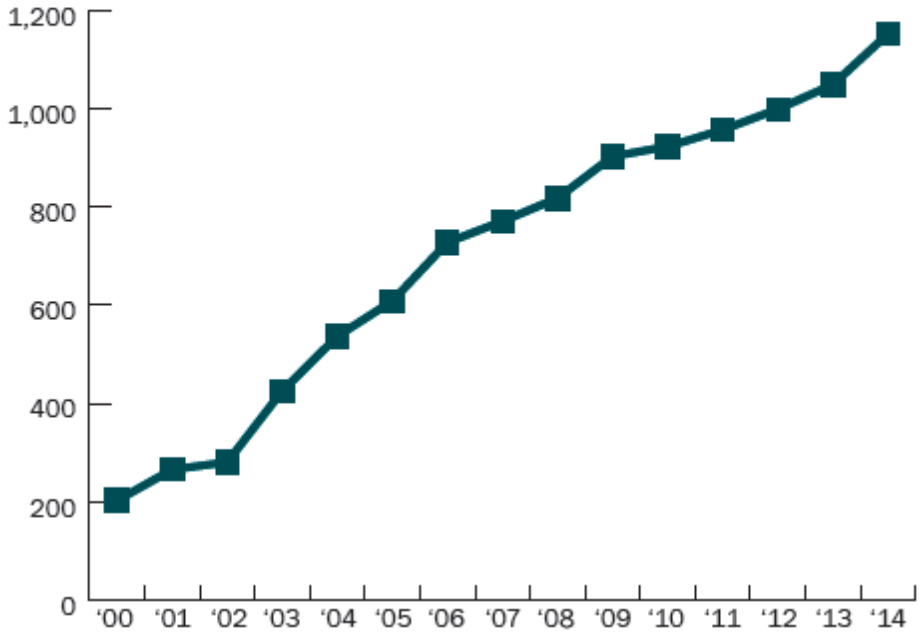
[243] *First Do No Harm*, at p. 3.

[244] *Id*.

[245] Gov.'s Task Force Rpt., at p. 6.

[246] *Id*., at p. 7.

FIGURE 1: Total Overdose Deaths, Indiana, 2000-2014[16]



411. Another chart shows that "[w]ith 1152 overdose deaths in 2014, Indiana ranks 15th in the nation. The number of deaths from drug overdoses has increased dramatically in the state since 1999, more than 500%.[247] Many of these deaths were caused by opioid overdose:[248]

[247] IU Rpt. on Opioid Use in Ind., at p. 6.

[248] *Id.*, at pp. 14–15.

Table 1 Number of Drug Overdose Deaths by Drug Type in Indiana, 1999-2014							
Year:	Heroin	Opioid pain relievers	Cocaine	Other & Unspecified Narcotics	Benzodia-zepines	Other & Unspecified Drugs	Total Drug Overdoses
1999	<5	25	27	15	7	99	184
2000	<5	24	14	9	<5	136	203
2001	<5	49	17	<5	7	172	266
2002	<5	43	27	14	10	195	281
2003	<5	92	36	26	21	291	426
2004	7	98	54	32	18	384	537
2005	13	118	46	31	25	447	609
2006	9	135	53	34	31	535	728
2007	16	195	52	32	45	559	771
2008	56	214	49	47	60	569	818
2009	65	259	41	18	96	663	903
2010	54	229	42	19	88	642	923
2011	63	250	33	46	90	712	957
2012	111	206	36	57	94	699	999
2013	152	168	45	51	74	703	1049
2014	170	250	47	61	84	792	1152

Data Notes: Counts under 5 are suppressed due to confidentiality. Total number of overdoses may not be equal to sum of all deaths. Death may have been included in more than one category if multiple drug codes are present.

Indiana State Department of Health, Epidemiology Resource Center, Data Analysis Team [24]

Many overdose deaths are categorized as "Other & Unspecified Drugs" but "[i]n reality, many of these deaths were likely related to opioid overdose, resulting in an understatement in the number of deaths from opioid pain relievers and heroin."[249]

412. On a whole, "[o]pioid-related death rates have risen from 4.5 per 100,000 population in 2008, to 11.7 per 100,000 in 2016. Drug deaths related to heroin have increased sharply beginning in 2011, and for synthetic opioids beginning in 2015."[250]

413. From 2008-2016, opioid poisoning deaths in Indiana per 100,000 residents were as follows:

a. 2008: 291 opioid deaths in Indiana; 4.5 opioid deaths in Indiana per 100,000 residents.

[249] *Id.*, at p. 15.

[250] NextLevel Recovery Indiana.

b. 2009: 322 opioid deaths in Indiana; 5.0 opioid deaths in Indiana per 100,000 residents.

c. 2010: 279 opioid deaths in Indiana; 4.3 opioid deaths in Indiana per 100,000 residents.

d. 2011: 345 opioid deaths in Indiana; 5.3 opioid deaths in Indiana per 100,000 residents.

e. 2012: 369 opioid deaths in Indiana; 5.7 opioid deaths in Indiana per 100,000 residents.

f. 2013: 352 opioid deaths in Indiana; 5.4 opioid deaths in Indiana per 100,000 residents.

g. 2014: 437 opioid deaths in Indiana; 6.7 opioid deaths in Indiana per 100,000 residents.

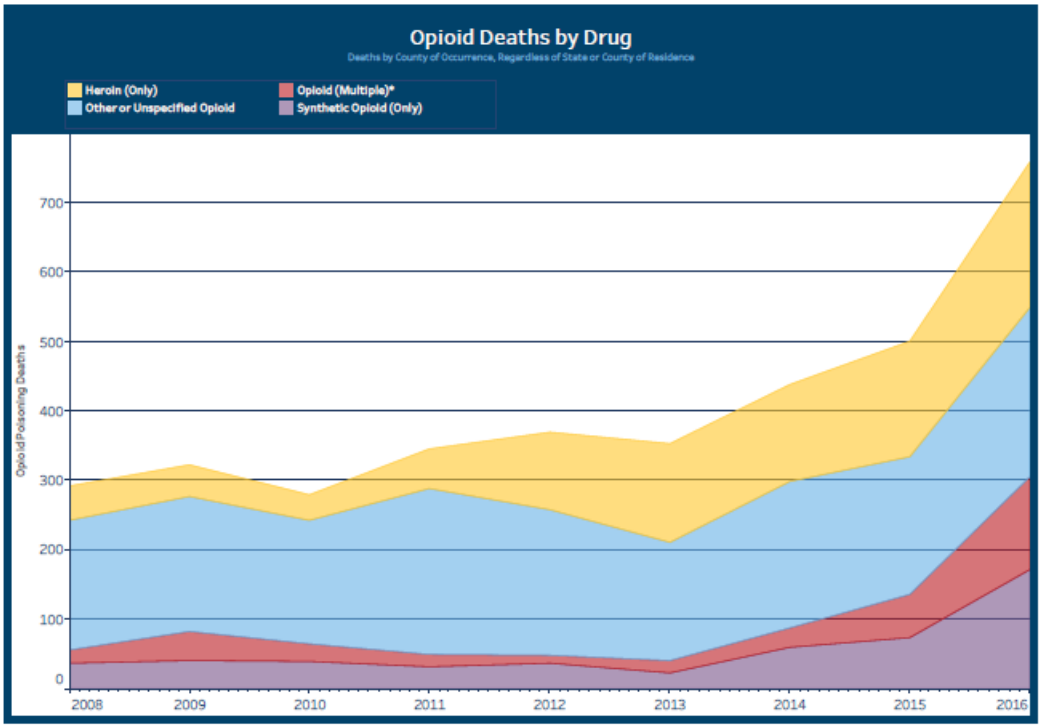
h. 2015: 499 opioid deaths in Indiana; 7.7 opioid deaths in Indiana per 100,000 residents.

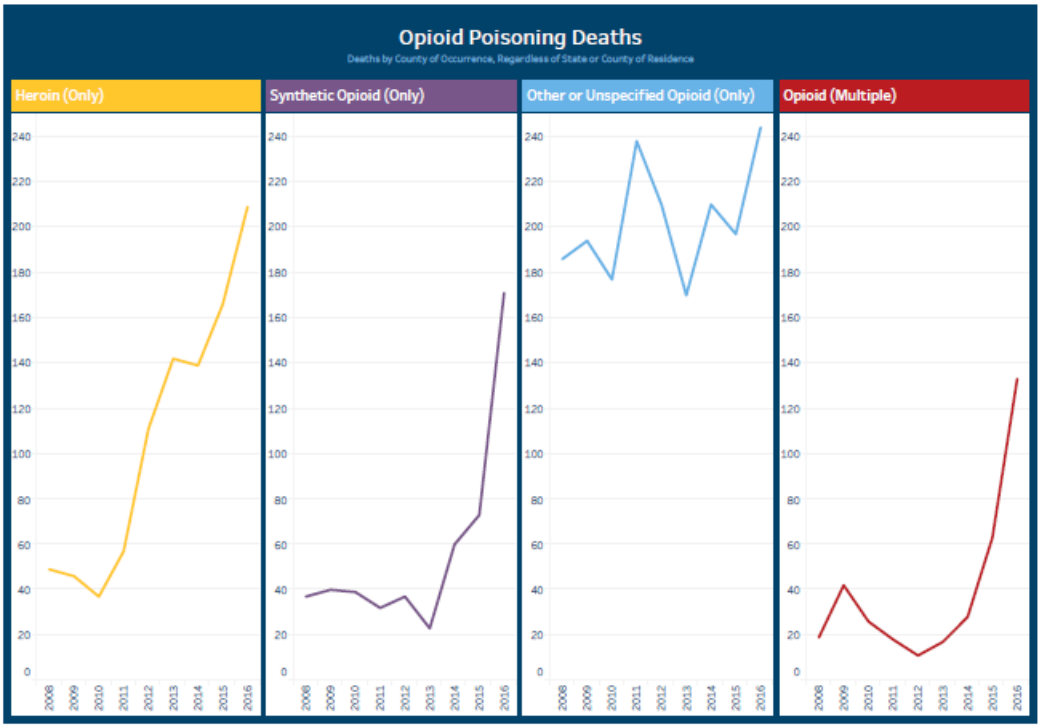
i. 2016: 757 opioid deaths in Indiana; 11.7 opioid deaths in Indiana per 100,000 residents.[251]

414. Charts of opioid poisoning deaths show the following:[252]

[251] *Id.*

[252] *Id.*


Opioid Deaths by Drug
Deaths by County of Occurrence, Regardless of State or County of Residence
Heroin (Only)
Opioid (Multiple)*
Other or Unspecified Opioid
Synthetic Opioid (Only)
Opioid Poisoning Deaths
0
100
200
300
400
500
600
700
2008
2009
2010
2011
2012
2013
2014
2015
2016


Opioid Poisoning Deaths
Deaths by County of Occurrence, Regardless of State or County of Residence
Heroin (Only)
Synthetic Opioid (Only)
Other or Unspecified Opioid (Only)
Opioid (Multiple)

415. "According to the Marshall County Health Department figures, the number of overdose deaths due to opioid and prescription drug abuse went from one in 2015 to 13 in 2016 and 16 already in 2017."[253]

TOLLING AND FRAUDULENT CONCEALMENT

416. Plaintiff continues to suffer harm from the unlawful actions by the Defendants.

417. The continued tortious and unlawful conduct by the Defendants causes a repeated or continuous injury. The damages have not occurred all at once but have continued to occur and have increased as time progresses. The harm is not completed nor have all the damages been incurred until the wrongdoing ceases. The wrongdoing and unlawful activity by Defendants has not ceased. The public nuisance remains unabated.

418. Defendants are equitably estopped from relying upon a statute of limitations defense because they undertook efforts to purposefully conceal their unlawful conduct and fraudulently assure the public, including Indiana and Marshall County, that they were undertaking efforts to comply with their obligations under the state and federal controlled substances laws, all with the goal of protecting their registered manufacturer or distributor status in the State and to continue generating profits. The Defendants affirmatively assured the public, including Indiana and Marshall County, that they are working to curb the opioid epidemic.

419. For example, a Cardinal Health executive said the company "deploys 'advanced analytics, technology, and teams of anti-diversion specialists and investigators who are

[253] Goodan, Anita, "Marshall County Commissioners to Consider Joining Opioid Litigation," *Max983.net*, 7 Nov. 2017. Web. 27 Nov. 2017.

embedded in our supply chain. This ensures that we are as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity.'"[254]

420. Moreover, in furtherance of their effort to affirmatively conceal their conduct and avoid detection, the Distributor Defendants, through their trade associations, HDMA and NACDS, filed a brief in *Masters Pharmaceuticals*, which made the following statements:

- "HDMA and NACDS members not only have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society."[255]

- "DEA regulations that have been in place for more than 40 years require distributors to *report* suspicious orders of controlled substances to DEA based on information readily available to them (e.g., a pharmacy's placement of unusually frequent or large orders)."[256]

- "Distributors take seriously their duty to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that *is* available to them in the ordering process. A particular order or series of orders can raise red flags because of its unusual size, frequency, or departure from typical patterns with a given pharmacy. Distributors also monitor for and report abnormal behavior by pharmacies placing orders, such as refusing to provide business contact information or insisting on paying in cash."[257]

421. Through the above statements made on their behalf by their trade associations, and other similar statements assuring their continued compliance with their legal obligations, the Distributor Defendants not only acknowledged that they understood their obligations under the

[254] Bernstein, Lenny et al., "How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: 'No one was doing their job,' *The Washington Post*, 22 Oct. 2016. Web. 6 Oct. 2017.

[255] Brief for HDMA and NACDS filed in *Masters Pharm., Inc. v. Drug Enf't Admin.*, USCA Case #15-1335, Doc. No. 1607110, p. 3 (D.C. Cir. Apr. 4, 2016).

[256] *Id.*, at p. 4.

[257] *Id.*, at p. 25.

law, but they further publicly affirmed that their conduct was in compliance with those obligations.

422. The Distributor Defendants have also concealed and prevented discovery of information, including data from the ARCOS database, that will confirm the extent of their wrongful and illegal activities.

423. The Manufacturer Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The Manufacturer Defendants invented the term "pseudoaddiction" and promoted it to an unsuspecting medical community. Manufacturer Defendants provided the medical community with false and misleading information about ineffectual medical strategies to avoid or control opioid addiction. Manufacturer Defendants recommended to the medical community that dosages be increased, without disclosing the risks. Manufacturer Defendants spent millions of dollars over a period of years on a misinformation campaign aimed at highlighting opioids' alleged benefits, disguising the risks, and promoting sales. The medical community, consumers, and Marshall County were duped by the Manufacturer Defendants' campaign to misrepresent and conceal the truth about the opioid drugs that they were aggressively pushing in the State and in Marshall County.

424. The Plaintiff reasonably relied on Defendants' affirmative statements regarding their purported compliance with their obligations under the law and consent orders.

425. The Plaintiff's claims are equitably tolled because Defendants knowingly and fraudulently concealed the facts and their wrongful acts, and the material information pertinent to their discovery, which Defendants concealed them from the Plaintiff. The Plaintiff did not know,

or could not have known through the exercise of reasonable diligence, of its claims, as a result of Defendants' conduct.

426. The purposes of the statutes of limitations period are satisfied because Defendants cannot claim prejudice due to a late filing where the Plaintiff filed suit promptly upon discovering the facts essential to its claims, described herein, which Defendants knowingly concealed.

427. In light of their statements to the media, in legal filings, and settlements, Defendants had actual and constructive knowledge that their conduct was deceptive, in that they consciously concealed the schemes set forth herein.

428. Defendants continually and secretly engaged in their scheme to avoid compliance with their legal obligations. Only Defendants and their agents knew or could have known about Defendants' unlawful actions because Defendants made deliberate efforts to conceal their conduct. As a result of the above, Plaintiff was unable to obtain vital information bearing on their claims absent any fault or lack of diligence on their part.

COUNT I:
PUBLIC NUISANCE
(AGAINST ALL DEFENDANTS)

429. Plaintiff incorporates and re-alleges each preceding paragraph of this Complaint as if fully set forth below.

430. "[T]he law of public nuisance is best viewed as shifting the resulting cost [of a public nuisance] from the general public to the party who creates it. If the marketplace values the product sufficiently to accept that cost, the manufacturer can price it into the product. If the manufacturers and users of the offending activity conclude that the activity is not worthwhile after absorbing these costs, that is their choice. In either case, there is no injustice in requiring the

activity to tailor itself to accept the costs imposed on others or cease generating them." *City of Gary ex rel. King v. Smith & Wesson Corp.*, 801 N.E.2d 1222, 1234 (Ind. 2003).

431. "The essence of a nuisance claim is the foreseeable harm unreasonably created by the defendants' conduct." *Id.*

432. Indiana Code § 32-30-6-6 provides that "[w]hatever is (1) injurious to health; (2) indecent; (3) offensive to the senses; or (4) an obstruction to the free use of property; so as essentially to interfere with the comfortable enjoyment of life or property, is a nuisance, and the subject of an action."

433. Indiana Code § 32-30-6-7(b) provides that "[a] civil action to abate or enjoin a nuisance may . . . be brought by: (a) the attorney representing the county in which a nuisance exists; or (b) the attorney of any city or town in which a nuisance exists." In addition, Indiana Code § 32-30-6-8 provides that "[i]f a proper case is made, the nuisance may be enjoined or abated and damages recovered for the nuisance." Finally, Indiana Code § 32-30-6-7(c) provides that "[a] county, city, or town that brings a successful action under this section to abate or enjoin a nuisance is entitled to recover reasonable attorney's fees incurred in bringing the action."

434. Defendants' activities have been, and continue to be, (1) injurious to health; (2) indecent; (3) offensive to the senses; or (4) an obstruction to the free use of property; so as essentially to interfere with the comfortable enjoyment of life and property, and constitute a nuisance.

435. Additionally, Defendants have created a public nuisance by creating an unreasonable interference with rights common to the general public in that:

a. Defendants' conduct involves a significant interference with the public health, the public safety, the public peace, the public comfort, and the public convenience;

b. Defendants' conduct is proscribed by statutes, and administrative regulations; and

c. Defendants' conduct is of a continuing nature and has produced a permanent and long-lasting effect, and Defendants know, and have reason to know, that their conduct has a significant effect upon public rights.

436. All Defendants are subject to liability because each Defendant has participated to a substantial extent in carrying out the activities that are the public nuisance.

COUNT II:
RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT,
18 U.S.C. § 1961, ET SEQ.
(AGAINST ALL DEFENDANTS)

437. Plaintiff incorporates and re-alleges each preceding paragraph of this Complaint as if fully set forth below.

438. Plaintiff brings this Count against all Defendants.

439. The Defendants conducted and continue to conduct their business through legitimate and illegitimate means in the form of an association-in-fact enterprise or a legal entity enterprise. At all relevant times, the Defendants were "persons" under 18 U.S.C. § 1961(3) because they are entities capable of holding, and do hold, "a legal or beneficial interest in property."

440. Section 1962(c) of RICO makes it unlawful "for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity or collection of unlawful debt." 18 U.S.C. § 1962(c); *United State v. Turkette*, 452 U.S. 576, 580 (1981).

441. The term "enterprise" includes "any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity." 18 U.S.C. § 1961(4); *Turkette*, 452 U.S. at 580; *Boyle v. United*

States, 556 U.S. 938, 944 (2009); *United Food & Commercial Workers Unions & Employers Midwest Health Benefits Fund v. Walgreen Co.*, 719 F.3d 849, 853 (7th Cir. 2013). The definition of "enterprise" in Section 1961(4) includes both legitimate and illegitimate enterprises. Specifically, the section "describes two separate categories of associations that come within the purview of an 'enterprise'—the first encompassing organizations such as corporations, partnerships, and other 'legal entities,' and the second covering 'any union or group of individuals associated in fact although not a legal entity.'" *Turkette*, 452 U.S. at 577. The second category is not a more generalized description of the first. *Id.*

442. For over a decade, the Defendants aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they sold. However, the Defendants are not permitted to engage in a limitless expansion of their market through the unlawful sales of regulated painkillers. As "registrants," the Defendants operated and continue to operate within the "closed-system" created under the Controlled Substances Act, 21 U.S.C. § 821, *et seq.* (the "CSA"). The CSA restricts the Defendants' ability to manufacture or distribute Schedule II substances like opioids by requiring them to: (1) register to manufacture or distribute opioids; (2) maintain effective controls against diversion of the controlled substances that they manufacturer or distribute; (3) design and operate a system to identify suspicious orders of controlled substances, halt such unlawful sales, and report them to the DEA; and (4) make sales within a limited quota set by the DEA for the overall production of Schedule II substances like opioids.

443. The closed-system created by the CSA, including the establishment of quotas, was specifically intended to reduce or eliminate the diversion of Schedule II substances like

opioids from "legitimate channels of trade" to the illicit market "by controlling the quantities of the basic ingredients needed for the manufacture of [controlled substances]."[258]

444. Finding it impossible to legally achieve their ever-increasing sales ambitions, members of the Opioid Diversion Enterprise (as defined below) systematically and fraudulently violated their statutory duty to maintain effective controls against diversion of their drugs, to design and operate a system to identify suspicious orders of their drugs, to halt unlawful sales of suspicious orders, and to notify the DEA of suspicious orders.[259] As discussed in detail below, through the Defendants' scheme, members of the Opioid Diversion Enterprise repeatedly engaged in unlawful sales of painkillers which, in turn, artificially and illegally increased the annual production quotas for opioids allowed by the DEA.[260] In doing so, the Defendants allowed hundreds of millions of pills to enter the illicit market which allowed them to generate enormous profits.

445. Defendants' illegal scheme was implemented by an association-in-fact enterprise between the Manufacturer Defendants and the Distributor Defendants, and executed by each of them. In particular, each of the Defendants was associated with, and conducted or participated in, the affairs of the RICO enterprise, whose purpose was to engage in the unlawful sales of opioids, deceive the public and federal and state regulators into believing that the Defendants were faithfully fulfilling their statutory obligations. The Defendants' scheme allowed them to make

[258] 1970 U.S.C.C.A.N. 4566 at 5490; *see also* Testimony of Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, *Drugcaucus.senate.gov*, U.S. Dept. of Justice, Drug Enforcement Administration, Before the Caucus on International Narcotics Control, United States Senate, 5 May 2015 ("Rannazzisi May 5, 2015 Testimony"). Web. 25 Oct. 2017.

[259] 21 U.S.C. § 823(a)(1), (b)(1); 21 C.F.R. § 1301.74(b)-(c).

[260] 21 C.F.R. § 1303.11(b); 21 C.F.R. § 1303.23.

billions in unlawful sales of opioids and, in turn, increase and maintain high production quotas with the purpose of ensuring unlawfully increasing revenues, profits, and market share. As a direct result of the Defendants' fraudulent scheme, course of conduct, and pattern of racketeering activity, they were able to extract billions of dollars of revenue, while Marshall County suffered injury caused by the reasonably foreseeable consequences of the opioid epidemic. As explained in detail below, the Defendants' misconduct violated Section 1962(c) and Plaintiff is entitled to treble damages for their injuries under 18 U.S.C. § 1964(c).

446. Alternatively, the Defendants were members of a legal entity enterprise within the meaning of 18 U.S.C. § 1961(4), through which the Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States. Specifically, the Healthcare Distribution Alliance (the "HDA")[261] is a distinct legal entity that satisfies the definition of a RICO enterprise. The HDA is a non-profit corporation formed under the laws of the District of Columbia and doing business in Virginia. As a non-profit corporation, HDA qualifies as an "enterprise" within the definition set out in 18 U.S.C. § 1961(4) because it is a corporation and a legal entity.

447. The Defendants are members, participants, and/or sponsors of the HDA and utilized the HDA to conduct the Opioid Diversion Enterprise and to engage in the pattern of racketeering activity that gives rise to the Count.

448. Each of the Defendants is a legal entity separate and distinct from the HDA. And, the HDA serves the interests of distributors and manufacturers beyond the Defendants. Therefore, the HDA exists separately from the Opioid Diversion Enterprise, and each of the

[261] Health Distribution Alliance, *History*, Health Distribution Alliance, *https://www.healthcaredistribution.org/about/hda-history*. Web. 11 Oct. 2017.

Defendants exists separately from the HDA. Therefore, the HDA itself serves as a RICO enterprise.

449. The legal and association-in-fact enterprises were each used by the Defendants to conduct the Opioid Diversion Enterprise by engaging in a pattern of racketeering activity. Therefore, the legal and association-in-fact enterprises are pleaded in the alternative and are collectively referred to as the "Opioid Diversion Enterprise."

I. The Opioid Diversion Enterprise

450. In 2006 and 2007, the DEA issued multiple letters to the Distributor Defendants reminding them of their obligation to maintain effective controls against diversion of particular controlled substances, to design and operate a system to disclose suspicious orders, and to inform the DEA of any suspicious orders.[262] The DEA also published suggested questions that a distributor should ask prior to shipping controlled substances, in order to know their customers.[263]

451. Central to the closed-system created by the CSA was the directive that the DEA determine quotas of each basic class of Schedule I and II controlled substances each year. The quota system was intended to reduce or eliminate diversion from "legitimate channels of trade" by controlling the "quantities of the basic ingredients needed for the manufacture of [controlled

[262] Joseph T. Rannazzisi, In Reference to Registration # RC0183080 (Sept. 27, 2006); Joseph T. Rannazzisi, In Reference to Registration # RC0183080 (Dec. 27, 2007).

[263] *See* "Suggested Questions a Distributor should ask prior to Shipping Controlled Substances, *Deadiversion.usdoj.gov/,* U.S. Dept. of Justice, Drug Enforcement Administration. Web. 11 Oct. 2017.

substances], and the requirement of order forms for all transfers of these drugs."[264] When evaluating production quotas, the DEA was instructed to consider the following information:

a. Information provided by the Department of Health and Human Services;

b. Total net disposal of the basic class by all manufacturers;

c. Trends in the national rate of disposal of the basic class;

d. An applicant's production cycle and current inventory position;

e. Total actual or estimated inventories of the class and of all substances manufactured from the class and trends in inventory accumulation; and

f. Other factors such as: changes in the currently accepted medical use of substances manufactured for a basic class; the economic and physical availability of raw materials; yield and sustainability issues; potential disruptions to production; and unforeseen emergencies.[265]

452. It is unlawful for a registrant to manufacture a controlled substance in Schedule II, like prescription opioids, that is (1) not expressly authorized by its registration and by a quota assigned to it by DEA, or (2) in excess of a quota assigned to it by the DEA.[266]

453. At all relevant times, the Defendants operated as an association-in-fact enterprise formed for the purpose of unlawfully increasing sales, revenues, and profits by disregarding their statutory duty to identify, investigate, halt, and report suspicious orders of opioids and diversion of their drugs into the illicit market, in order to unlawfully increase the quotas set by the DEA and allow them to collectively benefit from the unlawful formation of a greater pool of prescription opioids from which to profit. The Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States through this enterprise.

[264] 1970 U.S.C.C.A.N. 4566 at 5490; *see also* Rannazzisi May 5, 2015 Testimony.

[265] Rannazzisi May 5, 2015 Testimony, at p. 3.

[266] *Id.*, at p. 4 (citing 21 U.S.C. 842(b)).

454. At all relevant times, the Opioid Diversion Enterprise: (a) had an existence separate and distinct from each Defendant; (b) was separate and distinct from the pattern of racketeering in which the Defendants engaged; (c) was an ongoing and continuing organization consisting of legal entities, including each of the Defendants; (d) characterized by interpersonal relationships among the Defendants; (e) had sufficient longevity for the enterprise to pursue its purpose; and (f) functioned as a continuing unit. *Turkette*, 452 U.S. at 580; *Boyle*, 556 U.S. at 944. Each member of the Opioid Diversion Enterprise participated in the conduct of the enterprise, including patterns of racketeering activity, and shared in the astounding growth of profits supplied by fraudulently inflating opioid sales generated as a result of the Opioid Diversion Enterprise's disregard for their duty to prevent diversion of their drugs into the illicit market and then requesting the DEA increase production quotas, all so that the Defendants would have a larger pool of prescription opioids from which to profit.

455. The Opioid Diversion Enterprise also engaged in efforts to lobby against the DEA's authority to hold the Defendants liable for disregarding their duty to prevent diversion. Members of the Pain Care Forum (described in greater detail below) and the Healthcare Distribution Alliance ("HDA") lobbied for the passage of legislation to weaken the DEA's enforcement authority. The Ensuring Patient Access and Effective Drug Enforcement Act significantly reduced the DEA's ability to issue orders to show cause and to suspend and/or revoke registrations.[267] The HDA and other members of the Pain Care Forum contributed

[267] *See* "HDMA is now the Healthcare Distribution Alliance," *Pharmaceuticalcommerce.com*, 13 June 2016, updated 6 July 2016. Web. 11 Oct. 2017; Bernstein, Lenny et al, "Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control," *The Washington Post*, 22 Oct. 2016. Web. 6 Oct. 2017; Higham, Scott et al., "U.S. Senator Calls for Investigation of DEA Enforcement Slowdown amid Opioid Crisis," *The Washington Post*, 6 Mar. 2017. Web. 11 Oct. 2017; Eyre, Eric, "DEA

substantial amounts of money to political campaigns for federal candidates, state candidates, political action committees, and political parties. The Pain Care Forum and its members spent significant funds on lobbying efforts while the HDA devoted over a million dollars a year to its lobbying efforts between 2011 and 2016.

456. The Opioid Diversion Enterprise functioned by selling prescription opioids. While there are some legitimate uses and/or needs for prescription opioids, the Defendants, through their illegal enterprise, engaged in a pattern of racketeering activity, that involves a fraudulent scheme to increase revenue by violating State and Federal laws requiring the maintenance of effective controls against diversion of prescription opioids, and the identification, investigation, and reporting of suspicious orders of prescription opioids destined for the illicit drug market. The goal of Defendants' scheme was to increase profits from opioid sales. But, Defendants' profits were limited by the production quotas set by the DEA, so the Defendants refused to identify, investigate, and/or report suspicious orders of their prescription opioids being diverted into the illicit drug market. The end result of this strategy was to increase and maintain artificially high production quotas of opioids so that there was a larger pool of opioids for Defendants to manufacture and distribute for public consumption.

457. The Opioid Diversion Enterprise engaged in, and its activities affected, interstate and foreign commerce because the enterprise involved commercial activities across states lines, such as manufacture, sale, distribution, and shipment of prescription opioids throughout the County and this jurisdiction, and the corresponding payment and/or receipt of money from the sale of the same.

Agent: 'We Had no Leadership' in West Virginia Amid Flood of Pain Pills," *100daysinappalachia.com/*. Web. 25 Oct. 2017.

458. Within the Opioid Diversion Enterprise, there were interpersonal relationships and common communication by which the Defendants shared information on a regular basis. These interpersonal relationships also formed the organization of the Opioid Diversion Enterprise. The Opioid Diversion Enterprise used their interpersonal relationships and communication network for the purpose of conducting the enterprise through a pattern of racketeering activity.

459. Each of the Defendants had a systematic link to each other through joint participation in lobbying groups, trade industry organizations, contractual relationships, and continuing coordination of activities. The Defendants participated in the operation and management of the Opioid Diversion Enterprise by directing its affairs, as described herein. While the Defendants participated in, and are members of, the enterprise, they each have a separate existence from the enterprise, including distinct legal statuses, different offices and roles, bank accounts, officers, directors, employees, individual personhood, reporting requirements, and financial statements.

460. The Defendants exerted substantial control over the Opioid Diversion Enterprise by their membership in the Pain Care Forum, the HDA, and through their contractual relationships.

461. The Pain Care Forum ("PCF") has been described as a coalition of drugmakers, trade groups, and dozens of non-profit organizations supported by industry funding. The PCF recently became a national news story when it was discovered that lobbyists for members of the PCF quietly shaped federal and state policies regarding the use of prescription opioids for more than a decade.

462. The Center for Public Integrity and the Associated Press obtained "internal documents shed[ding] new light on how drugmakers and their allies shaped the national response to the ongoing wave of prescription opioid abuse."[268] Specifically, PCF participants spent over $740 million lobbying in the nation's capital and in all 50 statehouses on an array of issues, including opioid-related measures.[269]

463. Not surprisingly, each of the Defendants who stood to profit from lobbying in favor of prescription opioid use is a member of and/or participant in the PCF.[270] In 2012, membership and participating organizations included the HDA (of which all Defendants are members), Endo, Purdue, Johnson & Johnson, Actavis, and Teva.[271] Each of the Manufacturer Defendants worked together through the PCF to advance the interests of the enterprise. But, the Manufacturer Defendants were not alone. The Distributor Defendants actively participated, and continue to participate in the PCF, at a minimum, through their trade organization, the HDA.[272]

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[268] Perrone, Matthew, "Pro-Painkiller Echo Chamber Shaped Policy Amid Drug Epidemic," *The Center for Public Integrity*, 19 Sept. 2016, updated 15 Dec. 2016. Web. 25 Oct. 2017.

[269] *Id.*

[270] PAIN CARE FORUM 2012 Meetings Schedule, *https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-Meetings-Schedule-amp.pdf*, last updated Dec. 2011. Web. 11 Oct. 2017.

[271] *Id.*

[272] *Id.* The Executive Committee of the HDA (formerly the HDMA) currently includes the Chief Executive Officer, Pharmaceutical Segment for Cardinal Health, Inc., the Group President, Pharmaceutical Distribution and Strategic Global Source for AmerisourceBergen Corporation, and the President, U.S. Pharmaceutical for McKesson Corporation. *See* "Executive Committee, Healthcare Distribution Alliance," *Healthcaredistribution.org*, Healthcare Distribution Alliance. Web. 11 Oct. 2017.

464. The 2012 Meeting Schedule for the PCF is specific example of the Defendants' interpersonal relationships. The meeting schedule indicates that meetings were held in the D.C. office of Powers Pyles Sutter & Verville on a monthly basis, unless otherwise noted. Local members were "encouraged to attend in person" at the monthly meetings. And, the meeting schedule indicates that the quarterly and year-end meetings included a "Guest Speaker."

465. The 2012 PCF Meeting Schedule demonstrates that each of the Defendants participated in meetings on a monthly basis, either directly or through their trade organization, in a coalition of drugmakers and their allies whose sole purpose was to shape the national response to the ongoing prescription opioid epidemic, including the concerted lobbying efforts that the PCF undertook on behalf of its members.

466. Second, the HDA led to the formation of interpersonal relationships and an organization between the Defendants. Although the entire HDA membership directory is private, the HDA website confirms that each of the Distributor Defendants and the Manufacturer Defendants are members.[273] And, the HDA and each of the Distributor Defendants sought the active membership and participation of the Manufacturer Defendants by advocating that one of the benefits of membership included the ability to develop direct relationships between Manufacturers and Distributors at high executive levels.

467. In fact, the HDA touted the benefits of membership to the Manufacturer Defendants, advocating that membership included the ability to, among other things, "network one on one with manufacturer executives at HDA's members-only Business and Leadership Conference," "networking with HDA wholesale distributor members," "opportunities to host and

[273] "Manufacturer Membership," *Healthcaredistribution.org*, Healthcare Distribution Alliance, Web. 11 Oct. 2017.

sponsor HDA Board of Directors events," "participate on HDA committees, task forces and working groups with peers and trading partners," and "make connections."[274] The HDA and the Distributor Defendants used membership in the HDA as an opportunity to create interpersonal and ongoing organizational relationships between the Manufacturer and Distributor Defendants.

468. The application for manufacturer membership in the HDA further indicates the level of connection that existed between the Defendants.[275] The manufacturer membership application must be signed by a "senior company executive," and it requests that the manufacturer applicant identify a key contact and any additional contacts from within its company. The HDA application also requests that the manufacturer identify its current distribution information and its most recent year end net sales through any HDA distributors, including but not limited to, Defendants AmerisourceBergen, Cardinal Health, and McKesson.[276]

469. After becoming members, the Distributors and Manufacturers were eligible to participate on councils, committees, task forces and working groups, which promoted the Opioid Diversion Enterprise efforts, including lobbying and even development of chargebacks, including:

a. Industry Relations Council: "This council, composed of distributor and manufacturer members, provides leadership on pharmaceutical distribution and supply chain issues."[277]

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[274] "Manufacturer Membership Benefits," *Healthcaredistribution.org*, Healthcare Distribution Alliance. Web. 11 Oct. 2017.

[275] "Manufacturer Membership Application Instructions," *Healthcaredistribution.org*, Healthcare Distribution Alliance. Web. 11 Oct. 2017.

[276] *Id.*

[277] "Councils and Committees," *Healthcaredistribution.org*, Healthcare Distribution Alliance. Web. 11 Oct. 2017.

b. Business Technology Committee: "This committee provides guidance to HDA and its members through the development of collaborative e-commerce business solutions. The committee's major areas of focus within pharmaceutical distribution include information systems, operational integration and the impact of e-commerce." Participation in this committee includes distributors and manufacturer members.[278]

c. Health, Beauty and Wellness Committee: "This committee conducts research, as well as creates and exchanges industry knowledge to help shape the future of the distribution for health, beauty and wellness/consumer products in the healthcare supply chain." Participation in this committee includes distributors and manufacturer members.[279]

d. Logistics Operation Committee: "This committee initiates projects designed to help members enhance the productivity, efficiency and customer satisfaction within the healthcare supply chain. Its major areas of focus include process automation, information systems, operational integration, resource management and quality improvement." Participation in this committee includes distributors and manufacturer members.[280]

e. Manufacturer Government Affairs Advisory Committee: "This committee provides a forum for briefing HDA's manufacturer members on federal and state legislative and regulatory activity affecting the pharmaceutical distribution channel. Topics discussed include such issues as prescription drug traceability, distributor licensing, FDA and DEA regulation of distribution, importation and Medicaid/Medicare reimbursement." Participation in this committee includes manufacturer members.[281]

f. Bar Code Task Force: Participation includes Distributor, Manufacturer and Service Provider Members.[282]

g. eCommerce Task Force: Participation includes Distributor, Manufacturer and Service Provider Members.[283]

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[278] *Id.*

[279] *Id.*

[280] *Id.*

[281] *Id.*

[282] *Id.*

[283] *Id.*

h. ASN Working Group: Participation includes Distributor, Manufacturer and Service Provider Members.[284]

i. Contracts and Chargebacks Working Group: "This working group explores how the contract administration process can be streamlined through process improvements or technical efficiencies. It also creates and exchanges industry knowledge of interest to contract and chargeback professionals." Participation includes Distributor and Manufacturer Members.[285]

470. The councils, committees, task forces and working groups provided the Manufacturer and Distributor Defendants with the opportunity to work closely together in shaping their common goals and forming the enterprise's organization.

471. The HDA also offers a multitude of conferences, including annual business and leadership conferences. The HDA and the Distributor Defendants advertise these conferences to the Manufacturer Defendants as an opportunity to "bring together high-level executives, thought leaders and influential managers . . . to hold strategic business discussions on the most pressing industry issues."[286] The conferences also gave the Manufacturer and Distributor Defendants "unmatched opportunities to network with [their] peers and trading partners at all levels of the healthcare distribution industry."[287] The HDA and its conferences were significant opportunities for the Manufacturer and Distributor Defendants to interact at a high-level of leadership. And, it

[284] *Id.*

[285] *Id.*

[286] "Business and Leadership Conference – Information for Manufacturers," *Healthcaredistribution.org*, Healthcare Distribution Alliance. Web. 11 Oct. 2017.

[287] *Id.*

is clear that the Manufacturer Defendants embraced this opportunity by attending and sponsoring these events.[288]

472. Third, the Defendants maintained their interpersonal relationships by working together and exchanging information and driving the unlawful sales of their opioids through their contractual relationships, including chargebacks and vault security programs.

473. The Manufacturer Defendants engaged in an industry-wide practice of paying rebates and chargebacks to the Distributor Defendants for sales of prescription opioids.[289] As reported in the Washington Post, identified by Senator McCaskill, and acknowledged by the HDA, there is an industry-wide practice whereby the Manufacturer Defendants paid the Distributor Defendants rebates and/or chargebacks on their prescription opioid sales.[290] These contracts were negotiated at the highest levels, demonstrating ongoing relationships between the Manufacturer and Distributor Defendants. In return for the rebates and chargebacks, the Distributor Defendants provided the Manufacturer Defendants with detailed information regarding their prescription opioid sales, including purchase orders, acknowledgements, ship notices, and invoices.[291] The Manufacturer Defendants used this information to gather high-level

[288] *See* "2015 Distribution Management Conference and Expo," Healthcare Distribution Alliance, *Healthcaredistribution.org*, Healthcare Distribution Alliance. Web. 11 Oct. 2017.

[289] *See* Bernstein, Lenny et al., "The Government's Struggle to Hold Opioid Manufacturers Accountable," *The Washington Post*, 2 Apr. 2017. Web. 12 Oct. 2017. *See also* Letter from Sen. Claire McCaskill, *https://www.mccaskill.senate.gov/imo/media/image/july-opioid-investigation-letter-manufacturers.png*, 26 July 2017. Web. 12 Oct. 2017; "Behind an Epidemic: Opioid Manufacturers Subject of New McCaskill Investigation, *Mccaskill.senate.gov*. Web. 12 Oct. 2017; "Purdue Managed Markets," *Purduepharma.com*, Purdue Pharma. Web. 12 Oct. 2017.

[290] *See id.*

[291] *See* "Webinar Leveraging EDI: Order-to-Cash Transactions CD Box Set," *Healthcaredistribution.org*, Healthcare Distribution Alliance. Web. 11 Oct. 2017.

data regarding overall distribution and direct the Distributor Defendants on how to most effectively sell the prescription opioids.

474. The contractual relationships among the Defendants also include vault security programs. The Defendants are required to maintain certain security protocols and storage facilities for the manufacture and distribution of their opioids. Manufacturers likely negotiated agreements whereby the Manufacturers installed security vaults for Distributors in exchange for agreements to maintain minimum sales performance thresholds. These agreements were used by the Defendants as a tool to violate their reporting and anti-diversion duties.

475. Taken together, the interaction and length of the relationships between and among the Manufacturer and Distributor Defendants reflects a deep level of interaction and cooperation between two groups in a tightly knit industry. The Manufacturer and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. The Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids. The HDA and the PCF are but two examples of the overlapping relationships and concerted joint efforts to accomplish common goals and demonstrates that the leaders of each of the Defendants was in communication and cooperation.

476. According to articles published by the Center for Public Integrity and The Associated Press, the PCF has been lobbying on behalf of the Manufacturer and Distributor Defendants for "more than a decade."[292] And, from 2006 to 2016 the Distributor and

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[292] Perrone, Matthew, "Pro-Painkiller Echo Chamber Shaped Policy Amid Drug Epidemic," *The Center for Public Integrity,* 19 Sept. 2016, updated 15 Dec. 2016. Web. 25 Oct. 2017.

Manufacturer Defendants worked together through the PCF to spend over $740 million lobbying in the nation's capital and in all 50 statehouses on issues including opioid-related measures.[293] Similarly, the HDA has continued its work on behalf of Defendants, without interruption, since at least 2000, if not longer.[294]

477. As described above, the Defendants began working together as early as 2006 through the Pain Care Forum and the HDA to promote the common purpose of their enterprise. Defendants worked together as an ongoing and continuous organization throughout the existence of their enterprise.

II. Conduct of the Opioid Diversion Enterprise

478. During the time period alleged in this Complaint, the Defendants exerted control over, conducted and/or participated in the Opioid Diversion Enterprise by fraudulently failing to comply with their Federal and State obligations to identify, investigate and report suspicious orders of opioids in order to prevent diversion of those highly addictive substances into the illicit market, to halt such unlawful sales and, in doing so, to increase production quotas and generate unlawful profits, as follows:

479. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligations to maintain effective controls against diversion of their prescription opioids.

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[293] *Id.*

[294] "History," *Healthcaredistribution.org*, Healthcare Distribution Alliance. Web. 11 Oct. 2017.

480. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligations to design and operate a system to disclose to the registrant suspicious orders of their prescription opioids.

481. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligation to notify the DEA of any suspicious orders or diversion of their prescription opioids.

482. Defendants paid nearly $800 million dollars to influence local, state, and federal governments through joint lobbying efforts as part of the Pain Care Forum. The Defendants were all members of the PCF either directly or indirectly through the HDA. The lobbying efforts of the PCF and its members, included efforts to pass legislation making it more difficult for the DEA to suspend and/or revoke the Manufacturers' and Distributors' registrations for failure to report suspicious orders of opioids.

483. The Defendants exercised control and influence over the distribution industry by participating and maintaining membership in the HDA.

484. The Defendants applied political and other pressure on the DOJ and DEA to halt prosecutions for failure to report suspicious orders of prescription opioids and lobbied Congress to strip the DEA of its ability to immediately suspend registrations pending investigation by passing the "Ensuring Patient Access and Effective Drug Enforcement Act."[295]

[295] *See* "HDMA is now the Healthcare Distribution Alliance," *Pharmaceuticalcommerce.com*, 13 June 2016, updated 6 July 2016. Web. 11 Oct. 2017; Bernstein, Lenny et al, "Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control," *The Washington Post*, 22 Oct. 2016. Web. 6 Oct. 2017; Higham, Scott et al., "U.S. Senator Calls for Investigation of DEA Enforcement Slowdown amid Opioid Crisis," *The Washington Post*, 6 Mar. 2017. Web. 11 Oct. 2017; Eyre, Eric, "DEA Agent: 'We Had no Leadership' in West Virginia Amid Flood of Pain Pills," *100daysinappalachia.com/*. Web. 25 Oct. 2017.

485. The Defendants engaged in an industry-wide practice of paying rebates and chargebacks to incentivize unlawful opioid prescription sales. The Manufacturer Defendants used the chargeback program to acquire detailed, high-level data regarding sales of the opioids they manufactured. And the Manufacturer Defendants used this high-level information to direct the Distributor Defendants' sales efforts to regions where prescription opioids were selling in larger volumes.

486. The Manufacturer Defendants lobbied the DEA to increase Aggregate Production Quotas, year after year by submitting net disposal information that the Manufacturer Defendants knew included sales that were suspicious and involved the diversion of opioids that had not been properly investigated or reported by the Defendants.

487. The Distributor Defendants developed "know your customer" questionnaires and files. This information, compiled pursuant to comments from the DEA in 2006 and 2007 was intended to help the Defendants identify suspicious orders or customers who were likely to divert prescription opioids.[296] The "know your customer" questionnaires informed the Defendants of the number of pills that the pharmacies sold, how many non-controlled substances are sold compared to controlled substances, whether the pharmacy buys from other distributors, the types of medical providers in the area, including pain clinics, general practitioners, hospice facilities, cancer treatment facilities, and these questionnaires put the recipients on notice of suspicious orders.

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[296] *See* Widup, Richard et al., *"Pharmaceutical Production Diversion: Beyond the PDMA," Mcguirewoods.com.* Web. 12 Oct. 2017.

488. The Defendants refused to identify, investigate and report suspicious orders to the DEA when they became aware of them despite their actual knowledge of drug diversion rings. The Defendants refused to identify suspicious orders and diverted drugs despite the DEA issuing final decisions against the Distributor Defendants in 178 registrant actions between 2008 and 2012[297] and 117 recommended decision in registrant actions from The Office of Administrative Law Judges. These numbers include 76 actions involving orders to show cause and 41 actions involving immediate suspension orders—all for failure to report suspicious orders.[298]

489. Defendants' scheme had decision-making structure that was driven by the Manufacturer Defendants and corroborated by the Distributor Defendants. The Manufacturer Defendants worked together to control the state and federal governments' response to the manufacture and distribution of prescription opioids by increasing production quotas through a systematic refusal to maintain effective controls against diversion, and to identify and report suspicious orders to the DEA.

490. The Defendants worked together to control the flow of information and influence state and federal governments and politicians to pass legislation that benefitted Defendants. The Manufacturer and Distributor Defendants did this through their participation in the Pain Care Forum and HDA.

491. The Defendants also worked together to ensure that the Aggregate Production Quotas, Individual Quotas, and Procurement Quotas allowed by the DEA stayed high and ensured that suspicious orders were not reported to the DEA. By not reporting suspicious orders

[297] "The Drug Enforcement Administration's Adjudication of Registrant Actions," *Oig.justice.gov*, United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, I-2014-003, p. 6 (May 2014). Web. 25 Oct. 2017.

[298] *Id.*

or diversion of prescription opioids, the Defendants ensured that the DEA had no basis for decreasing or refusing to increase the production quotas for prescription opioids due to diversion of suspicious orders. The Defendants influenced the DEA production quotas in the following ways:

a. The Distributor Defendants assisted the enterprise and the Manufacturer Defendants in their lobbying efforts through the Pain Care Forum;

b. The Distributor Defendants invited the participation, oversight and control of the Manufacturer Defendants by including them in the HDA, including on the councils, committees, task forces, and working groups;

c. The Distributor Defendants provided sales information to the Manufacturer Defendants regarding their prescription opioids, including reports of all opioids prescriptions filled by the Distributor Defendants;

d. The Manufacturer Defendants used a chargeback program to ensure delivery of the Distributor Defendants' sales information;

e. The Manufacturer Defendants obtained sales information from QuintilesIMS (formerly IMS Health) that gave them a "stream of data showing how individual doctors across the nation were prescribing [opioids]."[299]

f. The Distributor Defendants accepted rebates and chargebacks for orders of prescription opioids;

g. The Manufacturer Defendants used the Distributor Defendants' sales information and the data from QuintilesIMS to instruct the Distributor Defendants to focus their distribution efforts to specific areas where the purchase of prescription opioids was most frequent;

h. The Defendants identified suspicious orders of prescription opioids and then continued filling those unlawful orders, without reporting them, knowing that they were suspicious and/or being diverted into the illicit drug market;

i. The Defendants refused to report suspicious orders of prescription opioids despite repeated investigation and punishment of the Distributor Defendants by the DEA for failure to report suspicious orders; and

[299] Ryan, Harriet et al., "More than 1 Million OxyContin Pills Ended up in the Hands of Criminals and Addicts. What the Drugmaker knew," *The Los Angeles Times*, 10 July 2016. Web. 25 Oct. 2017.

j. The Defendants withheld information regarding suspicious orders and illicit diversion from the DEA because it would have revealed that the "medical need" for and the net disposal of their drugs did not justify the production quotas set by the DEA.

492. The scheme devised and implemented by the Defendants amounted to a common course of conduct characterized by a refusal to maintain effective controls against diversion, and all designed and operated to ensure the continued unlawful sale of controlled substances.

III. Pattern of Racketeering Activity

493. The Defendants conducted and participated in the conduct of the Opioid Diversion Enterprise through a pattern of racketeering activity as defined in 18 U.S.C. § 1961(B), including mail fraud (18 U.S.C. § 1341) and wire fraud (18 U.S.C. § 1343); and 18 U.S.C. § 1961(D) by the felonious manufacture, importation, receiving, concealment, buying selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

A. The RICO Defendants Engaged in Mail and Wire Fraud.

494. The Defendants carried out, or attempted to carry out, a scheme to defraud federal and state regulators, and the American public, including Marshall County, by knowingly conducting or participating in the conduct of the Opioid Diversion Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. § 1961(1) that employed the use of mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).

495. The Defendants committed, conspired to commit, and aided and abetted in the commission of at least two predicate acts of racketeering activity (i.e. violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the RICO Defendants committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of

racketeering activity." The racketeering activity was made possible by the Defendants' regular use of the facilities, services, distribution channels, and employees of the Opioid Diversion Enterprise. The Defendants participated in the scheme to defraud by using mail, telephone, and the Internet to transmit mailings and wires in interstate or foreign commerce.

496. The Defendants used, directed the use of, and caused to be used, thousands of interstate mail and wire communications in service of their scheme through virtually uniform misrepresentations, concealments, and material omissions regarding their compliance with their mandatory reporting requirements and the actions necessary to carry out their unlawful goal of selling prescription opioids without reporting suspicious orders or the diversion of opioids into the illicit market.

497. In devising and executing the illegal scheme, the Defendants devised and knowingly carried out a material scheme and artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts. For the purpose of executing the illegal scheme, the Defendants committed these racketeering acts, which number in the thousands, intentionally and knowingly with the specific intent to advance the illegal scheme.

498. The Defendants' predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:

a. Mail Fraud: The Defendants violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

Wire Fraud: The Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

499. The Defendants' use of the mail and wires includes, but is not limited to, the transmission, delivery, or shipment of the following by the Manufacturers, Distributors, or third parties that were foreseeably caused to be sent as a result of the Defendants' illegal scheme, including but not limited to:

a. The prescription opioids themselves;

b. Documents and communications that facilitated the manufacture, purchase and unlawful sale of prescription opioids;

c. Defendants' DEA registrations;

d. Documents and communications that supported and facilitated Defendants' DEA registrations;

e. Documents and communications that supported and facilitated the Defendants' request for higher aggregate production quotas, individual production quotas, and procurement quotas;

f. Defendants' records and reports that were required to be submitted to the DEA pursuant to 21 U.S.C. § 827;

g. Documents and communications related to the Defendants' mandatory DEA reports pursuant to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74;

h. Documents intended to facilitate the manufacture and distribution of Defendants' prescription opioids, including bills of lading, invoices, shipping records, reports, and correspondence;

i. Documents for processing and receiving payment for prescription opioids;

j. Payments from the Distributors to the Manufacturers;

k. Rebates and chargebacks from the Manufacturers to the Distributors;

l. Payments to Defendants' lobbyists through the Pain Care Forum;

m. Payments to Defendants' trade organizations, like the HDA, for memberships and/or sponsorships;

n. Deposits of proceeds from Defendants' manufacture and distribution of prescription opioids; and

o. Other documents and things, including electronic communications.

500. The Defendants, for the purpose of executing the illegal scheme, sent and/or received (or caused to be sent and/or received) by mail or by private or interstate carrier, shipments of prescription opioids and related documents by mail or by private carrier affecting interstate commerce, including the following:

a. Purdue manufactures multiple forms of prescription opioids, including but not limited to: OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER. Purdue manufactured and shipped these prescription opioids to the Distributor Defendants in this jurisdiction. The Distributor Defendants shipped Purdue's prescription opioids throughout this jurisdiction.

b. Cephalon manufactures multiple forms of prescription opioids, including but not limited to: Actiq and Fentora. Cephalon manufactured and shipped these prescription opioids to the Distributor Defendants in this jurisdiction. The Distributor Defendants shipped Teva's prescription opioids throughout this jurisdiction.

c. Janssen manufactures prescription opioids known as Duragesic. Janssen manufactured and shipped its prescription opioids to the Distributor Defendants in this jurisdiction. The Distributor Defendants shipped Janssen's prescription opioids throughout this jurisdiction.

d. Endo manufactures multiple forms of prescription opioids, including but not limited to: Opana/Opana ER, Percodan, Percocet, and Zydone. Endo manufactured and shipped its prescription opioids to the Distributor Defendants in Ohio. The Distributor Defendants shipped Janssen's prescription opioids throughout this jurisdiction.

e. Actavis manufactures multiple forms of prescription opioids, including but not limited to: Kadin and Norco, as well as generic versions of the drugs known as Kadian, Duragesic, and Opana. Actavis manufactured and shipped its prescription opioids to the Distributor Defendants in this jurisdiction. The Distributor Defendants shipped Actavis's prescription opioids throughout this jurisdiction.

f. Mallinckrodt manufactures multiple forms of prescription opioids, including but not limited to: Exalgo and Roxicodone. The Distributor Defendants shipped Mallinckrodt's prescription opioids throughout this jurisdiction.

501. The Defendants also used the internet and other electronic facilities to carry out their scheme and conceal the ongoing fraudulent activities. Specifically, the Defendants made

misrepresentations about their compliance with Federal and State laws requiring them to identify, investigate, and report suspicious orders of prescription opioids and/or diversion of the same into the illicit market.

502. At the same time, the Defendants misrepresented the superior safety features of their order monitoring programs, ability to detect suspicious orders, commitment to preventing diversion of prescription opioids, and that they complied with all state and federal regulations regarding the identification and reporting of suspicious orders of prescription opioids.

503. Defendants also utilized the internet and other electronic resources to exchange communications, to exchange information regarding prescription opioid sales, and to transmit payments and rebates/chargebacks.

504. The Defendants also communicated by U.S. Mail, by interstate facsimile, and by interstate electronic mail and with various other affiliates, regional offices, regulators, distributors, and other third-party entities in furtherance of the scheme.

505. Several Defendants also entered into various Corporate Integrity Agreements with various entities, including the Office of Inspector General and the United States Department of Health and Human Services, that required the Defendants annually to certify in writing that the Defendants had implemented effective compliance programs and were otherwise in compliance with laws and regulations regarding, among other things, the manufacture and distribution of opioids. Defendants submitted through the mail and wires certifications that were false and misleading, in furtherance of the Opioid Diversion Enterprise's operation and goals, including false and misleading certifications required annually under the following:

a. Section V.j of the Deferred Prosecution Agreement entered in *United States of America v. Endo Pharmaceuticals, Inc.*, No. 1:14-CR-00066-MAD, ECF No. 2 (N.D.N.Y. Feb. 21, 2014);

b. Section III of the Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and Endo Pharmaceuticals, Inc. (fully executed on Feb. 21, 2014);

c. Section III of the Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and Johnson & Johnson (fully executed on Oct. 31, 2013); and

d. Section III of the Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and Purdue Pharma, L.P. (fully executed on May 8, 2007).

506. The mail and wire transmissions described herein were made in furtherance of Defendants' scheme and common course of conduct to deceive regulators and the public that Defendants were complying with their state and federal obligations to identify and report suspicious orders of prescription opioids all while Defendants were knowingly allowing millions of doses of prescription opioids to divert into the illicit drug market. The Defendants' scheme and common course of conduct was intended to increase or maintain high production quotas for their prescription opioids from which they could profit.

507. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities have been deliberately hidden, and cannot be alleged without access to Defendants' books and records. But, Plaintiff has described the types of, and in some instances, occasions on which the predicate acts of mail and/or wire fraud occurred. They include thousands of communications to perpetuate and maintain the scheme, including the things and documents described in the preceding paragraphs.

508. The Defendants did not undertake the practices described herein in isolation, but as part of a common scheme. These actions violate 18 U.S.C. § 1962(c). Various other persons, firms, and corporations, including third-party entities and individuals not named as defendants in this Complaint, may have contributed to and/or participated in the scheme with the Defendants in

these offenses and have performed acts in furtherance of the scheme to increase revenues, increase market share, and /or minimize the losses for the Defendants.

509. The Defendants aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§ 1341 and 1343 offenses.

510. The Defendants hid from the general public, and suppressed and ignored warnings from third parties, whistleblowers and governmental entities, about the reality of the suspicious orders that the Defendants were filling on a daily basis—leading to the diversion of tens of millions of doses of prescriptions opioids into the illicit market.

511. The Defendants, with knowledge and intent, agreed to the overall objective of their fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in manufacturing and distributing prescription opioids.

512. Indeed, for the Defendants' fraudulent scheme to work, each of the Defendants had to agree to implement similar tactics regarding marketing prescription opioids and refusing to report suspicious orders.

513. The Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

514. The predicate acts all had the purpose of generating significant revenue and profits for the Defendants while Plaintiff was left with substantial injury to their business through the damage that the prescription opioid epidemic caused. The predicate acts were committed or

caused to be committed by the Defendants through their participation in the Opioid Diversion Enterprise and in furtherance of its fraudulent scheme.

515. The pattern of racketeering activity and the Opioid Diversion Enterprise are separate and distinct from each other. Likewise, Defendants are distinct from the enterprise.

516. The pattern of racketeering activity is continuing as of the date of this Complaint and will continue into the future unless enjoined by this Court.

517. Many of the precise dates of the Defendants' criminal actions have been hidden and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the Opioid Diversion Enterprise alleged herein depended upon secrecy.

518. Each instance of racketeering activity was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including consumers in this jurisdiction and the Plaintiff. Defendants calculated and intentionally crafted the Opioid Diversion Enterprise and their scheme to increase and maintain their increased profits, without regard to the effect such behavior would have on Plaintiff, its residents, and its community. In designing and implementing the scheme, at all times Defendants knew that those in the manufacturing and distribution chain rely on the integrity of the pharmaceutical companies and ostensibly neutral third parties to provide objective and reliable information regarding Defendants' products and their manufacture and distribution of those products. The Defendants were also aware that Plaintiff and the citizens of this jurisdiction rely on the Defendants to maintain a closed system and to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

519. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

520. It was foreseeable to Defendants that refusing to report and halt suspicious orders, as required by the CSA and Code of Federal Regulations, would harm Plaintiff by allowing the flow of prescriptions opioids from appropriate medical channels into the illicit drug market.

521. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

B. The RICO Defendants Manufactured, Sold, and/or Dealt in Controlled Substances and Their Crimes Are Punishable as Felonies.

522. The Defendants conducted and participated in the conduct of the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity as defined in 18 U.S.C. § 1961(D) by the felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

523. The Defendants committed crimes that are punishable as felonies under the laws of the United States. Specifically, 21 U.S.C. § 483(a)(4) makes it unlawful for any person to knowingly or intentionally furnish false or fraudulent information in, or omit any material information from, any application, report, record, or other document required to be made, kept, or filed under this subchapter. A violation of section 483(a)(4) is punishable by up to four years in jail, making it a felony. 21 U.S.C. § 483(d)(1).

524. Each of the Defendants qualifies as a registrant under the CSA. Their status as registrants under the CSA requires that they maintain effective controls against diversion of controlled substances in schedule I or II, design and operate a system to disclose to the registrant

suspicious orders of controlled substances, and inform the DEA of suspicious orders when discovered by the registrant. 21 U.S.C. § 823; 21 C.F.R. § 1301.74(b).

525. Pursuant to the CSA and the Code of Federal Regulations, the RICO Defendants were required to make reports to the DEA of any suspicious orders identified through the design and operation of their system to disclose suspicious orders.

526. The Defendants knowingly and intentionally furnished false or fraudulent information in their reports to the DEA about suspicious orders, and omitted material information from reports, records, and other documents required to be filed with the DEA, including the Manufacturer Defendants' applications for production quotas. Specifically, the Defendants were aware of suspicious orders of prescription opioids and the diversion of their prescription opioids into the illicit market, and failed to report this information to the DEA in their mandatory reports and their applications for production quotas.

527. For example, the DEA and DOJ began investigating McKesson in 2013 regarding its monitoring and reporting of suspicious controlled substances orders. On April 23, 2015, McKesson filed a Form-8-K announcing a settlement with the DEA and DOJ wherein it admitted to violating the CSA and agreed to pay $150 million and have some of its DEA registrations suspended on a staggered basis. The settlement was finalized on January 17, 2017.[300]

528. Purdue's experience in Los Angeles is another striking example of Defendants' willful violation of the CSA and Code of Federal Regulations as it relates to reporting suspicious orders of prescription opioids. In 2016, the Los Angeles Times reported that Purdue was aware

[300] "McKesson Finalizes Settlement with U.S. Department of Justice and U.S. Drug Enforcement Administration to Resolve Past Claims," *Mckesson.com*, McKesson Corporation, 17 Jan. 2017. Web. 12 Oct. 2017.

of a pill mill operating out of Los Angeles yet failed to alert the DEA.[301] The LA Times uncovered that Purdue began tracking a surge in prescriptions in Los Angeles, including one prescriber in particular. A Purdue sales manager spoke with company officials in 2009 about the prescriber, asking "Shouldn't the DEA be contacted about this?" and adding that she felt "very certain this is an organized drug ring."[302] Despite knowledge of the staggering amount of pills being issued in Los Angeles, and internal discussion of the problem, "Purdue did not shut off the supply of highly addictive OxyContin and did not tell authorities what it knew about Lake Medical until several years later when the clinic was out of business and its leaders indicted. By that time, 1.1 million pills had spilled into the hands of Armenian mobsters, the Crips gang and other criminals."[303]

529. Mallinckrodt also was recently the subject of a DEA and Senate investigation for its opioid practices. Specifically, in 2011, the DEA targeted Mallinckrodt arguing that it ignored its responsibility to report suspicious orders as 500 million of its pills ended up in Florida between 2008 and 2012.[304] After six years of DEA investigation, Mallinckrodt agreed to a settlement involving a $35 million fine. Federal prosecutors summarized the case by saying that

[301] Ryan, Harriet et al., "More than 1 Million OxyContin Pills Ended up in the Hands of Criminals and Addicts. What the Drugmaker knew," *The Los Angeles Times*, 10 July 2016. Web. 25 Oct. 2017.

[302] *Id.*

[303] *Id.*

[304] Bernstein, Lenny et al., "The Government's Struggle to Hold Opioid Manufacturers Accountable," *The Washington Post*, 2 Apr. 2017. Web. 12 Oct. 2017. This number accounted for 66% of all oxycodone sold in the state of Florida during that time.

Mallinckrodt's response was that everyone knew what was going on in Florida but they had no duty to report it.[305]

530. These examples reflect the Defendants' pattern and practice of willfully and intentionally omitting information from their mandatory reports to the DEA as required by 21 C.F.R. § 1301.74. This conclusion is supported by the sheer volume of enforcement actions available in the public record against the Distributor Defendants. For example:

a. On April 24, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the AmerisourceBergen Orlando, Florida distribution center ("Orlando Facility") alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;

b. On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone;

c. On December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;

d. On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone;

e. On January 30, 2008, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Stafford, Texas Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;

f. On May 2, 2008, McKesson Corporation entered into an Administrative Memorandum of Agreement ("2008 MOA") with the DEA which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required

[305] *Id.*

by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program";

g. On September 30, 2008, Cardinal Health entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia ("McDonough Facility"), Valencia, California ("Valencia Facility") and Denver, Colorado ("Denver Facility");

h. On February 2, 2012, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of oxycodone;

i. On December 23, 2016, Cardinal Health agreed to pay a $44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center; and

j. On January 5, 2017, McKesson Corporation entered into an Administrative Memorandum Agreement with the DEA wherein it agreed to pay a $150,000,000 civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora CO, Aurora IL, Delran NJ, LaCrosse WI, Lakeland FL, Landover MD, La Vista NE, Livonia MI, Methuen MA, Santa Fe Springs CA, Washington Courthouse OH and West Sacramento CA.

531. These actions against the Distributor Defendants confirm that the Distributors knew they had a duty to maintain effective controls against diversion, design and operate a system to disclose suspicious orders, and to report suspicious orders to the DEA. These actions also demonstrate that the Manufacturer Defendants were aware of the enforcement against their Distributors and the diversion of the prescription opioids and a corresponding duty to report suspicious orders.

532. The pattern of racketeering activity is continuing as of the date of this Complaint and will likely continue into the future unless enjoined by this Court.

533. Many of the precise dates of Defendants' criminal actions were hidden and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the Opioid Diversion Enterprise depended upon the secrecy of the participants in that enterprise.

534. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiff, its residents, and its community. Defendants calculated and intentionally crafted the diversion scheme to increase and maintain profits from unlawful sales of opioids, without regard to the effect such behavior would have on this jurisdiction, its citizens or the Plaintiff. The Defendants were aware that Plaintiff and the citizens of this jurisdiction rely on the Defendants to maintain a closed system of manufacturing and distribution to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

535. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

536. It was foreseeable to Defendants that refusing to report and halt suspicious orders, as required by the CSA and Code of Federal Regulations would harm Plaintiff by allowing the flow of prescriptions opioids from appropriate medical channels into the illicit drug market.

537. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

IV. Damages

538. The Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiff's injury in its business and property because Plaintiff paid for costs associated with the opioid epidemic.

539. Plaintiff's injuries, and those of its residents and community, were proximately caused by Defendants' racketeering activities. But for the Defendants' conduct, Plaintiff would not have paid the health services and law enforcement services and expenditures required as a result of the plague of drug-addicted residents.

540. Plaintiff's injuries and those of their residents and community were directly caused by the Defendants' racketeering activities.

541. Plaintiff was most directly harmed and there is no other Plaintiff better suited to seek a remedy for the economic harms at issue here.

542. Plaintiff seeks all legal and equitable relief as allowed by law, including actual damages, treble damages, equitable relief, forfeiture as deemed proper by the Court, attorney's fees and all costs and expenses of suit and pre- and post-judgment interest.

COUNT III:
RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT, 18 U.S.C. § 1962(D), ET. SEQ.
(AGAINST ALL DEFENDANTS)

543. Plaintiff incorporates and re-alleges each preceding paragraph of this Complaint as if fully set forth below.

544. Plaintiff brings this claim on its own behalf against all Defendants. At all relevant times, the Defendants were associated with the Opioid Diversion Enterprise and agreed and conspired to violate 18 U.S.C. § 1962(c), that is, they agreed to conduct and participate, directly and indirectly, in the conduct of the affairs of the Opioid Diversion Enterprise through a pattern

of racketeering activity in violation of 18 U.S.C. § 1962(d). Under Section 1962(d) it is unlawful for "any person to conspire to violate" Section 1962(d), among other provisions. 18 U.S.C. § 1962(d).

545. Defendants conspired to violate Section 1962(c), as alleged more fully above, by conducting the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity, as incorporated by reference below.

I. The Opioid Diversion Enterprise

546. Plaintiff incorporates by reference Paragraphs 450 through 477 concerning the Opioid Diversion Enterprise.

II. Conduct of the Opioid Diversion Enterprise

547. Plaintiff incorporates by reference Paragraphs 478 through 492 concerning the Opioid Diversion Enterprise.

III. Pattern of Racketeering Activity

548. Plaintiff incorporates by reference Paragraphs 493 through 537 concerning the Opioid Diversion Enterprise.

IV. Damages

549. Plaintiff incorporates by reference Paragraphs 538 through 542 concerning the Opioid Diversion Enterprise.

COUNT IV:
NEGLIGENCE
(AGAINST ALL DEFENDANTS)

550. Plaintiff incorporates and re-alleges each preceding paragraph of this Complaint as if fully set forth below.

551. Defendants had an obligation to use reasonable care in manufacturing, marketing, selling, and distributing highly dangerous opioid drugs to Marshall County, and the injuries

alleged in this Complaint from the breach of that duty were foreseeable, and in fact were foreseen, by Defendants. *See City of Everett v. Purdue Pharma L.P. et al*., No. C17-209RSM, 2017 WL 4236062 at *4, 6-7 (W.D. Wash. Sept. 25, 2017) (sustaining a negligence claim by city against Purdue for damages caused by the opioid crisis).

552. Reasonably prudent manufacturers and distributors of prescription opioids would have anticipated that the scourge of opioid addiction would wreak havoc on communities, and the significant costs which would be imposed upon the governmental entities associated with those communities. The closed system of opioid distribution whereby wholesale distributors are the gatekeepers between manufacturers and pharmacies, and wherein all links in the chain have a duty to prevent diversion, exists for the purpose of controlling dangerous substances such as opioids and preventing diversion and abuse.

553. Reasonably prudent manufacturers of pharmaceutical products would know that aggressively pushing highly addictive opioids for chronic pain would result in the severe harm of addiction, foreseeably causing patients to seek increasing levels of opioids, frequently turning to the illegal drug market as a result of a drug addiction that was foreseeable to the Manufacturer Defendants.

554. Moreover, Defendants were repeatedly warned by law enforcement of the unlawfulness and consequences of their actions and omissions.

555. The escalating amounts of addictive drugs flowing through Defendants' businesses, and the sheer volume of these prescription opioids, further alerted Defendants that addiction was fueling increased consumption and that legitimate medical purposes were not being served.

556. Distributor Defendants breached their duties to exercise due care in the business of wholesale distribution of dangerous opioids, which are Schedule II Controlled Substances, by failing to monitor for, failing to report, and filling highly suspicious orders time and again. Because the very purpose of these duties was to prevent the resulting harm – diversion of highly addictive drugs for non- medical purposes – the causal connection between Defendants' breach of duties and the ensuing harm was entirely foreseeable.

557. Distributor Defendants misrepresented their compliance with their duties under the law and concealed their noncompliance and shipments of suspicious orders of opioids to Marshall County and destinations from which they knew opioids were likely to be diverted into Marshall County, in addition to other misrepresentations alleged and incorporated herein.

558. Manufacturer Defendants breached their duties to exercise due care in the business of pharmaceutical manufacturers of dangerous opioids, which are Schedule II Controlled Substances, and by misrepresenting the nature of the drugs and aggressively promoting them for chronic pain for which they knew the drug were not safe or suitable.

559. The Manufacturer Defendants misrepresented and concealed the addictive nature of prescription opioids and its lack of suitability for chronic pain, in addition to other misrepresentations alleged and incorporated herein.

560. All Defendants breached their duties to prevent diversion and report and halt suspicious orders, and all Defendants misrepresented their compliance with their legal duties.

561. Defendants' breaches were intentional and unlawful, and Defendants' conduct was willful, wanton, malicious, reckless, oppressive, and fraudulent.

562. The causal connection between Defendants' breaches of duties and misrepresentations and the ensuing harm was entirely foreseeable.

563. Defendants' breaches of duty and misrepresentations caused, bears a causal connection with, and proximately resulted in the damages sought herein.

564. Defendants were selling dangerous drugs statutorily categorized as posing a high potential for abuse and severe dependence. Defendants knowingly traded in drugs that presented a high degree of danger if prescribed incorrectly or diverted to other than medical, scientific, or industrial channels. However, Defendants breached their duties to monitor for, report, and halt suspicious orders, breached their duties to prevent diversion, and, further, misrepresented what their duties were and their compliance with their legal duties.

565. As a direct and proximate result of Defendants' breaches of duties, Plaintiff has been harmed and damaged.

COUNT V:
UNJUST ENRICHMENT
(AGAINST ALL DEFENDANTS)

566. Plaintiff incorporates and re-alleges each preceding paragraph of this Complaint as if fully set forth below.

567. "To prevail on a claim of unjust enrichment, a plaintiff must establish that a measurable benefit has been conferred on the defendant under such circumstances that the defendant's retention of the benefit without payment would be unjust." *Dominiack Mech., Inc. v. Dunbar*, 757 N.E.2d 186, 191 (Ind. Ct. App. 2001) (reversing dismissal of claim for unjust enrichment where defendants had received benefit from plaintiff through a third party) (citing *Bayh v. Sonnenburg*, 573 N.E.2d 398 (Ind. 1991)).

568. As set forth above, Plaintiff rendered a measurable benefit to the Defendants under such circumstances that Defendants' retention of the benefit without payment would be unjust. *See City of Everett*, No. C17-209RSM, 2017 WL 4236062, at *9 (Sustaining unjust

enrichment claim where City alleged Purdue Pharma profited immensely from its supply of opioids in the black market).

COUNT VI:
DAMAGES RESULTING FROM CIVIL CONSPIRACY
(AGAINST ALL DEFENDANTS)

569. Plaintiff incorporates and re-alleges each preceding paragraph of this Complaint as if fully set forth below.

570. "Indiana recognizes a cause of action for damages resulting from conspiracy." *SJS Refractory Co. v. Empire Refractory Sales, Inc.*, 952 N.E.2d 758, 769 (Ind. Ct. App. 2011).

571. "A civil conspiracy is a combination of two or more persons who engage in a concerted action to accomplish an unlawful purpose or to accomplish some lawful purpose by unlawful means." *Birge v. Town of Linden*, 57 N.E.3d 839, 845 (Ind. Ct. App. 2016) (reversing dismissal of civil conspiracy allegations where plaintiff alleged defendants conspired to create a public nuisance) (quoting *Miller v. Cent. Ind. Cmty. Found.*, 11 N.E.3d 944, 962 (Ind. Ct. App. 2014), *trans. denied.*

572. "It is not necessary in order to establish a conspiracy that there be direct evidence of an agreement." *Miller*, 11 N.E.3d at 944 (quoting *Tucker et al. v. Hyatt*, 151 Ind. 332, 51 N.E. 469 (1898)). "Rather, a civil conspiracy may be asserted through circumstantial evidence or by averment of isolated or independent facts susceptible of an inference of concurrence of sentiment." *Id.* (quoting *Moore v. Fletcher*, 136 Ind. App. 478, 196 N.E.2d 422 (1964), *trans. denied*).

573. "Each participant in the conspiracy may be held responsible as a joint tortfeasor for damages caused by the wrongful or contemptuous acts regardless of the degree of active participation." *SJS Refractory Co.*, 952 N.E.2d at 769.

574. Indiana courts have held that a claim for damages exists for a civil conspiracy to create a public nuisance or to commit other tortious acts. *See,e.g., Birge v. Town of Linden*, 57 N.E.3d at 845.

575. As set forth above in detail, Defendants conspired to create a public nuisance and to commit the tortious conduct alleged in this complaint and are therefore jointly and severally liable for the damages flowing from the conspiracy.

CLAIM FOR RELIEF

WHEREFORE, Plaintiff respectfully asks the Court to grant the following relief:

576. Enter Judgment in favor of the Plaintiff in a final order against each of the Defendants;

577. Order that Defendants compensate the Plaintiff for past and future costs to abate the ongoing public nuisance caused by the opioid epidemic;

578. Order Defendants to fund an "abatement fund" for the purposes of abating the opioid nuisance;

579. Award actual damages, treble damages, fines, injunctive and equitable relief, forfeiture as deemed proper by the Court, and attorneys' fees and all costs and expenses of suit pursuant to Plaintiff's racketeering claims;

580. Award the Plaintiff the damages caused by the opioid epidemic, including (A) costs for providing medical care, additional therapeutic and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths; (B) costs for providing treatment, counseling, and rehabilitation services; (C) costs for providing treatment of infants born with opioid-related medical conditions; (D) costs for providing care for children whose parents suffer from opioid-related disability or

incapacitation; and (E) costs associated with law enforcement and public safety relating to the opioid epidemic; and

581. Award such other relief as the Court deems proper.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury of any and all issues in this action so triable of right.

Respectfully submitted,

Dated: January 25, 2018

/s/ Lynn A. Toops

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